

Youth with type 1 diabetes: A study of their epidemiological and clinical characteristics, glycaemic control and psychosocial predictors, and an evaluation of the efficacy of Motivational Interviewing in improving diabetes management

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## **ABSTRACT**

Poorly controlled diabetes is common among the majority of youth with type 1 diabetes and can lead to adverse health outcomes at an early age. There is a need to change this to minimise the risk of negative long-term consequences. The onset of complications from diabetes can be prevented or delayed with good management as demonstrated by blood glucose being kept close to or within the normal range. Diabetes control is challenging for young people due to a combination of physiological and psychological factors.

Diabetes control needs to be monitored both at an individual level and also at a population level, in order to optimise health outcomes and provide important information for health service provision. There are gaps in knowledge relating to the current level of diabetes control at a population level and of the epidemiological characteristics of youth with type 1 diabetes in the Canterbury region in New Zealand. There has been no research of this nature in the Canterbury region since 2003. There are also gaps in knowledge and a lack of national and international research that investigates psychosocial characteristics of youth with type 1 diabetes and the impact these may have on diabetes control. There is a potentially promising intervention, namely, Motivational Interviewing (MI), that although previous research investigating it with diabetes has shown some promise, methodological problems have limited the conclusions that can be drawn. This thesis, within the New Zealand context, addresses some of these gaps and adds to the body of knowledge of research concerning diabetes control and youth with type 1 diabetes, and investigates MI intervention for youth with poorly controlled diabetes.

The thesis encompasses three studies. The first study is an audit that provides up-to-date information on epidemiological characteristics and clinical outcomes for the youth population with type 1 diabetes residing in the Canterbury region. The second

study is a cross-sectional study that investigates the relationship between glycaemic control and key psychosocial characteristics: illness beliefs, self-efficacy, and quality of life in youth with type 1 diabetes in Canterbury. The third study is a longitudinal study that investigates the efficacy of MI as an intervention for youth with poorly controlled type 1 diabetes, and explores its impact on diabetes outcomes using statistical and clinical analyses.

The first study showed that from 2003 to 2010 the prevalence of adolescents and young adults with type 1 diabetes in Canterbury has increased; there is therefore an increased demand on health resources. In addition, in 2010 glycaemic control at a population level was in the poorly controlled diabetes range and this had remained unchanged since 2003. This suggests the need for more intensive interventions. The second study found that poor diabetes control in youth with type 1 diabetes is influenced by a number of factors, including negative views on diabetes, lower perceived personal control, higher diabetes-related concerns, and lower levels of worry about complications. These findings provide a new understanding of the importance of balancing worries about diabetes complications and the perception of diabetes as a threatening condition. The third study showed that the MI intervention was generally successful in improving diabetes outcomes – clinical, psychosocial, and behavioural changes were observed. Statistically and clinically significant positive changes were found across multiple variables: glycated haemoglobin (HbA1c), glycaemic variability, adherence, and psychosocial functioning.

Taken together, the findings of the three studies indicate that majority of youth with type 1 diabetes in the Canterbury region had poor glycaemic control, which suggests that additional interventions may be required to improve management of their condition, especially interventions targeting psychosocial functioning (e.g., illness perceptions) and diabetes self-management. Motivational Interviewing may be a viable option, and therefore further research into this approach is recommended.

# Chapter 1

## *Introduction*

*Overview of diabetes mellitus, and  
background to the current study  
on youth with type 1 diabetes and  
diabetes management*

## CHAPTER 1: INTRODUCTION

### Overview of the Thesis

The current research aims to contribute to the research on improving diabetes outcomes for youth with type 1 diabetes. The target age range in this thesis is 15-24 years old; this age group is referred to as *youth* and is differentiated from childhood (0-14 years old) and adulthood (25-64 years old) for diabetes groups (Alberti & Zimmet, 2011; UNESCO, 2014; United Nations, 2013). The study cohort is from the Canterbury region in New Zealand. The thesis starts with an overview of diabetes, then moves to an overview of type 1 diabetes and its management. The thesis comprises three main studies, the first two studies describe and investigate specific characteristics of the target population, and the third study trials an intervention for youth with poorly controlled type 1 diabetes.

In brief, the first study is an *audit* to provide up-to-date information on epidemiological characteristics and clinical outcomes for the youth population who have type 1 diabetes, and who reside in the Canterbury region in New Zealand. The second study is a cross-sectional study of specific diabetes-related psychosocial factors and their relationship to diabetes control. The third study is a longitudinal study that investigates the efficacy of Motivational Interviewing (MI) as an intervention for youth with poorly controlled type 1 diabetes.

The current study had the support of the Canterbury District Health Board (CDHB) Diabetes Centre facilitated by the Diabetes Centre Manager, in consultation with relevant CDHB staff. Approvals for relevant parts of the study were granted by the Upper South B Regional Ethics Committee (URB/10/EXP/048), the University of

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The three studies of this thesis (i.e., audit, psychosocial evaluation, and MI intervention) are presented in separate chapters. Each chapter provides a review of the literature on theoretical and empirical knowledge related to the subject of the study, the aims and significance of the study, the methodological basis of the study, analysis of data, interpretation of the results, and discussion. A summary of key findings, conclusions, recommendations, and future directions follow these chapters to conclude the thesis. The present chapter provides an overview and background on type 1 diabetes and its management.

### **Diabetes Mellitus**

Diabetes mellitus is a complex metabolic disorder that is associated with abnormalities in controlling blood glucose levels (Alberti & Zimmet, 2011; Amiel, 2011). The regulation of blood glucose is vital for health and proper functioning of the body and brain. The blood glucose regulation process involves transporting glucose from the blood into cells in the body so it can be used for energy – this is the main action of insulin, a hormone that is produced in the pancreas (Hanas, 2007; Heller, 2011). Diabetes is caused by the body failing to produce insulin to regulate the blood.

The classification of diabetes types is based on the diagnosis of insulin

secretion and action and its impact on blood glucose levels (Alberti & Zimmet, 2011). Three of the main classifications are: type 1 diabetes, in which insulin secretion is critically defective as a result of the destruction of the insulin releasing cells in the pancreas; type 2 diabetes, in which there is abnormal insulin secretion, or abnormal insulin action, or both; and gestational diabetes, which occurs during pregnancy due to glucose intolerance, arising from an insufficient production of insulin during pregnancy (Alberti & Zimmet, 2011). The former two types are chronic conditions, whereas the latter type is temporary and may resolve after pregnancy (Alberti & Zimmet, 2011).

At present, although there is no cure for chronic diabetes conditions, ongoing treatment using medications and diabetes self-management is essential to avoid or prevent diabetes-related complications such as heart and kidney diseases (Atkinson & Eisenbarth, 2001). Diabetes management is a complicated process, and is influenced by many factors, including physiological, psychological, behavioural, and social factors (Delamater, de Wit, McDarby, Malik, & Acerini, 2014; Madsen, Roisman, & Collins, 2002; Moran et al., 2002). In addition to the individual patient's diabetes-management challenges, there are challenges for the health system (International Diabetes Federation, 2013; Ministry of Health, 2014). These include planning and accessibility of resources, such as medication, equipment, and access to appropriately trained health care professionals. Despite advanced medical treatments and modern health initiatives, poor diabetes control is common and persistent amongst individuals with diabetes (Nam, Chesla, Stotts, Kroon, & Janson, 2011). This has costly consequences and places a heavy burden on health systems at a global level (International Diabetes Federation, 2013).

Diabetes has become an increasing burden on health systems because of its complexity and rapidly increasing incidence rate (International Diabetes Federation, 2013; Sicree, Shaw, & Zimmet, 2009). The incidence rate and prevalence of diabetes is increasing nationally and internationally (Onkamo, Vaananen, Karvonen, & Tuomilehto, 1999; Wild, Roglic, Green, Sicree, & King, 2004; Willis et al., 2002). The incidence rate represents the rate of occurrence of new presentations of a disease during a particular period of time (Boniol & Heanue, 2007; Boyle & Parkin, 1991). The prevalence quantifies the proportion of patients with a certain condition in relevance to the entire population at a given time (Boniol & Heanue, 2007; Boyle & Parkin, 1991). This disorder is a global epidemic (International Diabetes Federation, 2013; Unwin, 2011; Whiting, Guariguata, Weil, & Shaw, 2011). Globally, it is estimated that more than 387 million people have diabetes and this estimation is likely to markedly increase by 2035 (International Diabetes Federation, 2013, 2014).

In New Zealand, the estimated national prevalence of diagnosed cases of diabetes in 2013 was 243,125, with an increase of 7.2% from 2005 (Jo & Drury, 2015; Ministry of Health, 2015). The estimated prevalence by district health board (DHB) domicile is 275,000–290,000 by end of 2015 (Ministry of Health, 2014). Diabetes is a major and increasing cause of premature death and disability in New Zealand and its prevalence is substantial, making it a top health priority for the New Zealand government (Jo & Drury, 2015; Ministry of Health, 2014). Health organisations worldwide, including those in New Zealand, have been investigating and implementing strategies to reduce the incidence and impact of diabetes (Diabetes Research Institute, n.d.; Ministry of Health, 2014).

Research on diabetes is needed to inform health professionals and those

involved in the care of patients to reduce the impact of diabetes and achieve optimal diabetes outcomes (Diabetes Research Institute, n.d.; Fonseca, Kirkman, Darsow, & Ratner, 2012). Research into the following components is required: epidemiological characteristics (e.g., prevalence and incidence rates), evaluation of clinical outcomes at a population level (e.g., diabetes control biomarkers levels), influential psychosocial factors (e.g., assessment of treatment barriers and illness perceptions), and effective interventions (e.g., educational, psychological, and behavioural interventions) (Diabetes Research Institute, n.d.; International Diabetes Federation, 2013; Ministry of Health, 2014). Research into diabetes needs to consider the type of diabetes to be studied, clinical aspects of that type, the target groups, and diabetes management for the type of diabetes being studied (Fonseca et al., 2012). Type 1 diabetes, a prevalent condition in young people, was selected for the current study.

### **Type 1 diabetes in Young People**

Type 1 diabetes is a serious condition that has a peak onset in childhood and adolescence (Alberti & Zimmet, 2011). Although type 1 diabetes can develop at any age, it is prevalent in those younger than 26 years old (Scott et al., 2006). The morbidity and mortality rates in young people diagnosed with diabetes are higher than the rates for those without diabetes (Borch-Johnsen, 1989; Laing et al., 1999a, 1999b). Diagnosis at an early age (< 15 years old), compared to diagnosis in adulthood, increases the risk for developing complications from diabetes (Harvey & Allagoa, 2004). Furthermore, during youth, negative or positive behaviours related to diabetes management develop, and these may have a critical impact on future diabetes management and health outcomes (Wysocki, Hough, Ward, & Green, 1992). Youth are vulnerable for sustained poorly controlled diabetes, and global studies



have shown that the majority of youth do not meet recommended clinical targets and may need more intensive interventions (Anderson et al., 2014; Daneman & Hamilton, 2001; Holl et al., 2003; Mortensen & Hougaard, 1997; Tan, Shafiee, Wu, Rizal, & Rey, 2005). This is discussed in the following sections.

Management of type 1 diabetes in young people is challenging and is influenced by developmental factors that include biological and psychological changes, particularly during adolescence years when diabetes control often deteriorates (Borus & Laffel, 2010; Hamilton & Daneman, 2002; Pinhas-Hamiel et al., 2014). The physiological aspects include pubertal and hormonal changes which are accompanied by increased biological requirements for insulin (Borus & Laffel, 2010). Psychological aspects include emotional distress, developing self-identity, and seeking autonomy (Borus & Laffel, 2010; Helgeson, Escobar, Siminerio, & Becker, 2010; Lerman-Garber et al., 2003; McCallister, 2006).

### **Type 1 Diabetes**

Type 1 diabetes is an autoimmune disease that is identified by a deficiency in insulin because of the destruction of insulin-secreting cells (beta-cells) in the pancreas, which are attacked by the body's immune system (Amiel, 2011). The body mistakenly identifies these cells as foreign and, as a consequence, attacks and isolates them, in a process that inhibits insulin production (Amiel, 2011). The precise mechanisms underlying type 1 diabetes are still not fully understood, and these as well as the risk factors for the development of type 1 diabetes are still the subject of research (Atkinson & Eisenbarth, 2001; Xie, Chang, & Zhou, 2014). Some potential risk factors for type 1 diabetes that have been identified are: genetic, environmental, hormonal, or a combination of these. There are genetic markers that confer increased

risk for type 1 diabetes; for example, when a member of a family has type 1 diabetes other members of that family may be susceptible to developing it (Savage & Bain, 2011; Xie et al., 2014). Nonetheless, not having the high risk genes does not preclude the development of type 1 diabetes. Environmental factors also play a role in the development of type 1 diabetes; however, it is still unclear as to what exactly these factors are, or what combinations increase the risk for developing diabetes (Knip et al., 2005; Xie et al., 2014). Possible environmental causes include viruses, cold weather and cow milk proteins (Knip et al., 2005). Hormones, such as growth and stress hormones, are factors that may inhibit the action of insulin and this can also lead to the development of diabetes (Hanas, 2007; Knip et al., 2005). The rapid growth at early puberty increases the risk for developing type 1 diabetes when beta-cells come under stress to produce more insulin because growth hormones hinder insulin action (Chowdhury, 2015). The onset of diabetes can be triggered by defective beta-cells, which are put under pressure because of highly demanding physiological changes (Knip et al., 2005). In addition, psychological stress, which increases the secretion of the cortisol hormone may obstruct insulin action (American Diabetes Association, 2008; Hägglöf, Blom, Dahlquist, Lönnerberg, & Sahlin, 1991; Hanas, 2007).

Lack of insulin secretion into the blood stream causes abnormalities in glucose concentration levels (American Diabetes Association, 2014; Atkinson & Eisenbarth, 2001). This can negatively impact on a person's physical and cognitive functioning (Kodl & Seaquist, 2008). Individuals with type 1 diabetes may experience symptoms such as excessive thirst and extreme hunger, fatigue, increased urination, unexplained weight loss, mood swings, abdominal pain, nausea, vomiting, blurred vision, skin infections, and poor concentration and performance (Hanas,

2007). These symptoms may indicate a diagnosis of diabetes, which can be confirmed using clinical biomarkers that are tested and analysed at a medical laboratory.

The diagnosis of type 1 diabetes involves analysing results from specific glucose tests that may include: fasting blood glucose, random (non-fasting) blood glucose, oral glucose tolerance, and haemoglobin *A1c* (HbA1c) tests (Alberti & Zimmet, 2011; American Diabetes Association, 2014). The fasting blood glucose test measures the blood glucose level in a person who has not eaten for several hours. A random blood glucose test, as the name suggests, is a blood sample taken at a random time (regardless of when they have eaten last) to measure the blood glucose level. The oral glucose tolerance test involves several blood tests taken to measure how the body reacts to glucose (glucose tolerance); a blood test precedes an oral intake of glucose followed by several tests at fixed intervals within a two hour time frame. The HbA1c assay measures the average blood glucose levels over the preceding 2-3 months by measuring the amount of glucose attached to haemoglobin in red blood cells. This is also referred to as glycated haemoglobin (Hanas, John, & International HbA1c Consensus Committee, 2014). Each test has clinical cut-off levels which can indicate whether an individual has a pre-diabetic condition or diabetes. A combination of tests may be required to confirm a diagnosis. There are international guidelines for the diagnosis criteria which have been well-documented (American Diabetes Association, 2014; World Health Organization, 2011).

### **Glycated Haemoglobin**

Haemoglobin *A1c* is considered the gold-standard to monitor the progress of the diabetes condition, the effectiveness of treatment, and the risk for developing

diabetes-related complications (Bruns, 2007; Hanas et al., 2014). The measurement and reporting of HbA1c has been standardised worldwide (Little et al., 2001; Weykamp et al., 2008). A commonly used standardised reference system is sourced from the National Glycohemoglobin Standardization Program (NGSP) protocol, whereby the reporting of the HbA1c level is depicted in a percentage unit (percentage of glycated haemoglobin) with at most one decimal place (e.g., HbA1c = 7.5%) (Little et al., 2001). More recently, an updated system was implemented by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), which uses the mmol/mol units with no decimal places (e.g., HbA1c = 55 mmol/mol) (Mosca et al., 2007). Specific equations can be used to convert values between the NGSP and IFCC systems (NZSSD, 2011). Globally, IFCC is a recommended system for reporting HbA1c, and this has replaced the NGSP system in many countries, including New Zealand (Mosca et al., 2007). The HbA1c laboratory data was formally changed in New Zealand in late 2011 to report HbA1c in the IFCC units (Florkowski & Crooke, 2010; Florkowski, Crooke, & Reed, 2014; NZSSD, 2009a, 2011). In the current study, the IFCC unit is used; however, original units used in the reviewed literature will be reported.

The New Zealand Society for the Study of Diabetes (NZSSD), which is the national advisory body on scientific and clinical diabetes care and standards in New Zealand, has provided guidelines for individual targets for HbA1c (see Table 1.1) (NZSSD, 2009b). There are also international guidelines that specify HbA1c targets for youth. The International Society for Pediatric and Adolescent Diabetes (ISPAD) recommends an HbA1c less than 7.5% (58 mmol/mol) for those aged 13-19, and a lower level (7%; 53 mmol/mol) for adults (ISPAD & International Diabetes Federation, 2011). The above guidelines are generic targets and recommendations

may vary across individuals. The NZSSD standards for HbA1c levels and classifications are used for the current study. In Table 1.1, it can be noted that in addition to the classification of diabetes control levels there are indications for the risk of developing diabetes-related complications. There are two types of diabetes-related complications: short-term and long-term. These are presented in greater detail in following sections.

**Table 1.1**

*HbA1c value (mmol/mol) targets and diabetes control categories (NZSSD, 2009b)*

HbA1c mmol/mol	diabetes control category
< 50	Excellent control; increased risk of hypoglycaemia if on insulin/sulphonylureas
50-54	Very good control; some risk of hypoglycaemia if on insulin/sulphonylureas
55-64	May be appropriate and acceptable in many individuals but higher than ideal from clinical trial evidence. Microvascular complication risk increases exponentially above around 55mmol/mol
65-79	Suboptimal glycaemic control. Consider more intensive treatment. Microvascular complication risk increases exponentially above around 55mmol/mol
80-99	Poor glycaemic control. More intensive treatment recommended. Microvascular complication risk increases exponentially above around 55
> 100	Very poor glycaemic control. Warrants immediate action

The recommended HbA1c targets, as stated earlier, can be achieved through a complicated management process that addresses issues associated with the diabetes condition including insulin deficiency and unregulated blood glucose (Hanas, 2007). This complex process requires the involvement of a multidisciplinary team (including physicians, dietitians, diabetes nurses, psychologists, and diabetes educators), and the individual who has diabetes and their family. Many aspects are taken into consideration in this process, such as comorbidity, psychological status,

and an individual's age and lifestyle; thus, treatment plans differ amongst individuals (McNabb, 1997).

### **Management of Type 1 Diabetes**

*Diabetes management* refers to the process of controlling blood glucose by means of restoring carbohydrate metabolism to a near normal state (Hanas, 2010). Diabetes management aims to address abnormalities in the glucose concentration levels in the blood because of the defective insulin-secretion (Hanas, 2010). Diabetes management also refers to dealing with high and low blood glucose levels in the short term to be able to meet the long term goals recommended for diabetes control (Hanas, 2010).

Diabetes management is not a straightforward task and involves a system of medical, behavioural, and psychosocial processes, which include diabetes self-management tasks, and diabetes-oriented lifestyle adjustments (Borus & Laffel, 2010; Hanas, 2010; Reed, 2014). These are part of a daily regimen, which incorporate four main components: blood glucose monitoring, insulin mediation, diet, and exercise (Hanas, 2007; Reed, 2014).

There are generic guidelines that address these components for type 1 diabetes (CDHB, 2015; Diabetes New Zealand, 2014; Reed, 2014). As an example, diabetes self-management includes adjusting insulin medication according to specific dietary intakes. Individuals with type 1 diabetes are expected to adjust their insulin dosage to suit their carbohydrate intake shortly after meal time or snack (e.g., within 15 minutes), with a prospect of a three meals per day and at least one snack. Ideally, the insulin dosage would be enough to cover the number of units counted from the

carbohydrates they eat (1 unit = 15 grams of carbohydrates). In addition, they are advised to have regular exercise (at least three times per week) to help break down the glucose in the blood, and also to coordinate medication and monitor blood glucose levels to avoid immediate complications from having low blood glucose levels.

Adherence to recommendations for the diabetes self-management has been shown to have a positive impact on diabetes outcomes (Asche, LaFleur, & Conner, 2011; Hood, Peterson, Rohan, & Drotar, 2009). Adherence refers to the level of engagement to the recommended diabetes self-management behaviours and lifestyle adjustments (e.g., blood glucose monitoring and insulin dose adjustments) (Delamater, 2006). Measurement of adherence mostly involves using self-report measures (e.g., log diaries, adherence recall interviews, and scales such as the Self-Care Inventory). Blood glucose monitoring adherence, however, can be measured more objectively (rather than merely by self-report) by means of downloading blood glucose readings from blood glucose monitors (Budde, 2009).

Self-monitoring of blood glucose (SMOBG) is an essential component of diabetes self-management (Hanas, 2010; Rewers et al., 2014). This provides instant feedback on current blood glucose levels which individuals with type 1 diabetes can use to inform their daily management of blood glucose levels. Research has reported significant correlations between frequent SMOBG and lower and improved HbA1c (e.g., Anderson et al., 2014; Rewers et al., 2014; Ziegler et al., 2011). Furthermore, SMOBG can be used to evaluate glycaemic variability and this is also associated with changes in HbA1c and the risk for complications; this is discussed shortly.

A portable blood glucose monitoring device is usually recommended so that

individuals with diabetes can check their glucose levels as part of their daily self-management routine (Hanas, 2010). There is a range of blood glucose readings, also referred to as the *practically observed range*, which many blood glucose monitoring devices can display. This range includes blood glucose readings from 1.1 to 33.3 mmol/L (Kovatchev, Cox, Kumar, Gonder-Frederick, & Clarke, 2003). Clinical studies recommend classifications for blood glucose levels to differentiate low or high blood glucose values that may lead to severe hypoglycaemia or hyperglycaemia. These are: normal blood glucose (euglycaemia), 3.9-10 mmol/L; low blood glucose (hypoglycaemia),  $1.1 < \text{blood glucose} < 3.9$  mmol/L; and high blood glucose (hyperglycaemia),  $10 < \text{blood glucose} < 33.3$  mmol/L (DCCT Research Group, 1993; Robeva et al., 2007). Values that are less than 2.2 mmol/L are considered to be extreme hypoglycaemia, and those that exceed 22.2 mmol/L are considered to be evidence of extreme hyperglycaemia (Kovatchev et al., 2003).

Blood glucose values outside of the euglycaemia range can have negative consequences and result in a person experiencing various diabetes-related symptoms or complications (Shaw & Cummings, 2012). These symptoms and complications can range from *unpleasant* to *acute* depending on the extent and severity of changes in blood glucose concentration (Amiel, 2011; Choudhary & Amiel, 2011; Clarke, Jones, Rewers, Dunger, & Klingensmith, 2009; Wass & Owen, 2014). Change in blood glucose concentration in a given time is referred to as glycaemic excursion. Glycaemic excursions contribute to forming a profile of blood glucose fluctuations or glycaemic variability (GV) (Krishna, Kota, & Modi, 2013).

Reducing GV has the potential to contribute to improved diabetes control and to reduce the risk of complications (DeVries, 2013; Krishna et al., 2013). The HbA1c



measures glycaemic control using an averaged value over a considerable time period; however, it does not capture GV of intra-day and inter-day data found in a blood glucose profile (Dailey, 2007; Tylee & Trence, 2012). The evaluation of GV provides information on the quality of blood glucose profiles and may account for the frequency and level of hypoglycaemia and hyperglycaemia excursions (i.e., mild, moderate, or severe excursions) (Dailey, 2007; Kovatchev, Otto, Cox, Gonder-Frederick, & Clarke, 2006; Kovatchev, Straume, Cox, & Farhy, 2000). In simple words, GV measures the quality of blood glucose fluctuations and extent of peaks and nadirs in glycaemic excursions (Tylee & Trence, 2012). Methods for measuring GV are presented in Chapter 4.

### **Diabetes Complications**

Poorly controlled diabetes may result in a range of complications, including physiological damage and cognitive dysfunction (Choudhary & Amiel, 2011; Donaghue, Chiarelli, Trotta, Allgrove, & Dahl-Jorgensen, 2009; Nathan, 1993; Wass & Owen, 2014). There are short-term and long-term complications linked to poorly controlled diabetes. Hypoglycaemia and hyperglycaemia are two forms of short-term complications, and may lead to the development of other severe conditions. Untreated or persistent hypoglycaemia and hyperglycaemia increase the risk of developing critical complications that can be life threatening (e.g., coma and death) or long-lasting (e.g., heart and kidney diseases) (Nathan, 1993). Thus, preventing or avoiding short-term complications can minimise the risk of critical and long-term complications (Nathan et al., 2009).

Long-term diabetes complications include the development of microvascular and macrovascular diseases (Donaghue et al., 2009). The former affects smaller

blood vessels leading to nephropathy (kidney disease), neuropathy (nerve damage), and retinopathy (eye disease). The latter affects larger blood vessels and leads to cardiovascular diseases, such as circulation disorders and heart failure. Clinical trials have shown that tight control of diabetes reduces the risk for complications (DCCT Research Group, 1993, 2002; Fullerton et al., 2014; Nordwall et al., 2015). To achieve tight control typically involves intensive medical treatment, frequent monitoring of blood glucose, and strict adherence to recommendations of diabetes self-management (e.g., insulin mediation, diet, and exercise). The intensive medical regime may involve taking frequent insulin medications, which may include at least three insulin injections per day corresponding to meal or snack consumption. Insulin injections are an attempt to mimic insulin secretion from the pancreas and so achieve blood glucose levels that are within the healthy range in non-diabetic individuals. There is, however, a risk of experiencing severe hypoglycaemia associated with the intensive and tight control in the attempt to achieve lower HbA1c (DCCT Research Group, 1997; Fowler, 2008; Havlin & Cryer, 1988). Nevertheless, safely reaching recommended HbA1c values, through the tight daily management and blood glucose control, has been shown to reduce microvascular and macrovascular complications to a significant extent (DCCT Research Group, 1993, 2002).

A large controlled clinical trial of 1,441 subjects (aged 13-39) with type 1 diabetes showed that a reduction of 1% in HbA1c (i.e., 11 mmol/mol) significantly reduced the risk for diabetes complications of retinopathy, nephropathy, neuropathy, and cardiovascular conditions (DCCT Research Group, 1993, 1996). A related study showed that the risk of complications can be potentially eliminated if long-term HbA1c is maintained below 60 mmol/mol (Nordwall et al., 2015). This study found that none of the participants (aged under 35) with long-term HbA1c below 60

mmol/mol developed retinopathy or nephropathy, when followed up over a 20 year period. In contrast, 51% of those with poorly controlled diabetes (long-term HbA1c of 80 mmol/mol) developed retinopathy and chronic nephropathy. It is therefore crucial for people with type 1 diabetes to maintain good diabetes control, and reductions in HbA1c for those with HbA1c above recommended levels can contribute to a substantial decrease in the risk for long-lasting complications. This is not as simple as it seems and, as noted earlier, is influenced by a number of factors, especially for those in the youth developmental stage.

### **Poor Diabetes Control in Youth**

Poor diabetes control is common for the majority of adolescents and young adults and there is a global documentation of this (Anderson et al., 2014; Daneman & Hamilton, 2001; Holl et al., 2003; Mortensen & Hougaard, 1997). The largest international, contemporary, study found that the majority of young people (8-25 year olds) with type 1 diabetes were not meeting recommended glucose control targets (Anderson et al., 2014; Laffel et al., 2014). This cross-sectional and observational study recruited nearly 6000 participants from 20 countries (Europe, USA, Latin America, Middle East, Africa, and India). The study found nearly three-quarters (72%) of the young people had HbA1c above the recommended level, with higher percentages in the age groups 13-25 year olds. The overall HbA1c means for adolescents aged 13-18 ( $n = 2854$ ) and young adults aged 19-25 ( $n = 1382$ ) were 8.6% and 8.4%, respectively. Only, about a third (29%) of the adolescents and a fifth (19%) of young adults met the recommended targets, with one in five having an HbA1c that was extremely high ( $\geq 10\%$ ). These results are consistent with findings from previous global audits that found the majority of youth with type 1 diabetes did

not meet targets for HbA1c and presented an overall HbA1c average that was above 8% (e.g., Holl et al., 2003; Mortensen & Hougaard, 1997).

Key findings from the above study suggested that targets for healthy diabetes control may be achieved by improving behavioural and psychosocial aspects related to diabetes management (Anderson et al., 2014; Laffel et al., 2014). Factors that were found to be associated with achieving target HbA1c, as identified in multivariate analysis, included: monitoring blood glucose at least three times a day, carbohydrate counting, regular exercise, no history of diabetic ketoacidosis in the previous 3 months, diabetes related family conflict, and an absence of financial burden related to diabetes management. Moreover, the study found that better quality of life for young people is significantly associated with better diabetes control. The findings suggest that whilst the majority of youth with type 1 diabetes are not meeting the HbA1c targets, diabetes control can be improved and the impact of diabetes can be reduced (Anderson et al., 2014; Laffel et al., 2014). Control of diabetes in youth with type 1 diabetes can be achieved by targeting the factors that can be modified and so help youth meet the recommended HbA1c targets (Anderson et al., 2014; Laffel et al., 2014; Svoren, Butler, Levine, Anderson, & Laffel, 2003).

The current status of diabetes management can be generally summarised by a statement by Nam et al. (2011) in his systematic review of barriers to diabetes management: “despite significant advances in diagnosis and treatment, the persistence of inadequate metabolic control continues. Poor glycemic control may be reflected by both the failure of diabetes self-management by patients as well as inadequate intervention strategies by clinicians” (p. 1).

This chapter provided an overview of diabetes mellitus and diabetes

management particularly in youth with type 1 diabetes, all relevant as background to the three studies in this thesis. Diabetes is a complex metabolic disorder that is becoming a global epidemic. Type 1 diabetes is prevalent in those younger than 26 years old (Scott et al., 2006) and although it cannot be cured, it can be managed so that blood glucose levels are maintained within the healthy range in non-diabetic individuals. Diabetes management is not a straightforward task and involves engagement in multiple diabetes self-management behaviours and diabetes-oriented lifestyle adjustments (Hanas, 2007). Management of type 1 diabetes in young people is challenging and is influenced by developmental factors that include physiological and psychological changes, particularly during adolescence years when diabetes control often deteriorates (Borus & Laffel, 2010; Hamilton & Daneman, 2002; Pinhas-Hamiel et al., 2014).

The next chapter presents an audit of the demographics, prevalence of type 1 diabetes, and glycaemic control for youth in Canterbury, New Zealand.

# Chapter 2

## *Audit*

*Youth with type 1 diabetes: an audit of the demographics, prevalence of type 1 diabetes, and glycaemic control for youth in Canterbury, New Zealand*

## **CHAPTER 2: AUDIT**

### **Introduction**

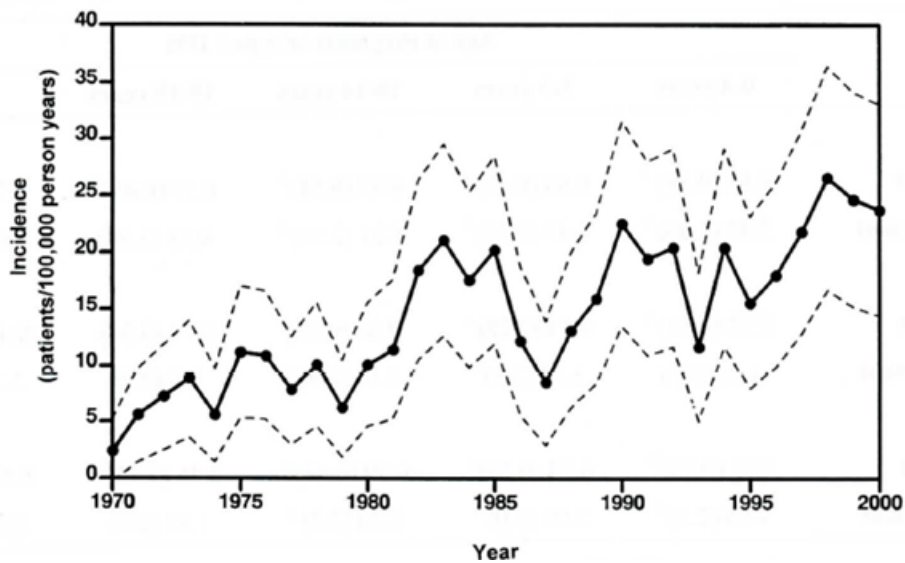
This chapter presents the first study in the thesis, which is an audit of the demographics, prevalence, and diabetes control of youth (15-24 year olds) with type 1 diabetes in the CDHB catchment area, and an exploration of changes in the prevalence and diabetes control outcomes. This study was published in the New Zealand Medical Journal (Obaid, Britt, Wallace-Bell, & Johnson-Elsmore, 2012a), and presented at the 36th Annual Scientific Meeting the New Zealand Society for the Study of Diabetes (Obaid, Britt, Wallace-Bell, & Johnson-Elsmore, 2012b, 2012c). The following is a review of literature relevant to the current study.

### **Youth with Type 1 Diabetes in Canterbury**

The incidence rate of children and adolescents (0-19 years) with type 1 diabetes over a period of 30 years was previously investigated in the Canterbury region (Willis et al., 2002). The study by Willis et al. (2002) analysed the number of newly diagnosed cases from 1970 to 1999 as to whether there were any changes in the incidence rates over time. The analysis involved collating data obtained from clinical registers, including the Canterbury Register of Insulin Treated Persons (Brown & Scott, 1988). Records of hospital admissions, and inpatient and outpatient clinics were also accessed. Secondary sources of information included General Practitioner (GP) records, community-based surveys, and direct contact with patients and their families. The study reported that 100% of individuals with type 1 diabetes were identified with no missing cases.

The incidence of type 1 diabetes for those younger than 20 years in Canterbury was found to have significantly increased over time, with a 3.4-fold increase in the number of type 1 diabetes presentations between 1970 and 1999 (Willis et al., 2002). The increase in age-gender specific incidence rate of type 1 diabetes over time was statistically significant in females and males 0-14 years old, with the exception for females aged 0-4 years. In contrast, the change in rate of new presentations of type 1 diabetes in both age-gender groups in adolescents (15-19 years old) with time was not significant (Willis et al., 2002). For children less than 12 years of age, the number of males exceeded the number of females with type 1 diabetes over the entire period (i.e., from 1970 to 1999). From 1990-1999 it was observed that the difference between number of males and females with type 1 diabetes was consistent across all ages after 5 years of age, in which males always exceeded females (Willis et al., 2002). Ethnicity was not considered for analyses, because of the small number of non-European presentations of type 1 diabetes in Canterbury. The total number of incident cases in this study was 474 (256 males, and 218 females), with the lowest incidence rate (2.40 per 100,000 person-years) recorded in 1970 and the highest incidence rate (26.59 per 100,000 person-years) recorded in 1998. The dramatic increase in incidence rate of type 1 observed from 1970 to 1999, Figure 2.1, follows a global trend of rapidly increasing presentations of type 1 diabetes (Willis et al., 2002).





**Figure 2.1.** The incidence of type 1 diabetes in children and adolescents, aged < 20 years, in Canterbury, New Zealand, 1970-2000 (- - - 95% CI); source: Willis et al. (2002, p. 639).

The prevalence of type 1 diabetes in children and young adults (0-24 year olds) in the CDHB region was investigated in 2003 (Wu et al., 2005). The CDHB catchment area was defined to include the city of Christchurch, the town of Ashburton, and rural areas around North Canterbury. Records of children and young adults were obtained from clinical and research registers of CDHB diabetes services. The study database was cross-checked for completeness; checks were carried out on records retrospectively with a back date of two and a half year since the start of the study. The records were obtained from the Christchurch Hospital, Ashburton Diabetes Clinic, and community-focused diabetes services.

This study reported an estimated prevalence of 227 per 100,000 population for young people with type 1 diabetes in the CDHB catchment area (Wu et al., 2005). The study found a total of 353 young people with diagnoses of diabetes in the Canterbury region, with 330 individuals diagnosed with type 1 diabetes. Of those

individuals with type 1 diabetes, 168 (51%) were males and 307 (93%) were of European descent. Stratified data of age-specific European New Zealanders with type 1 diabetes showed that the majority were adolescents (15-19 years old) and young adults (20-24 years old);  $n = 92$  (30%) and 95 (31%), respectively. That is, of the total number of European New Zealanders with type 1 in the CDBH catchment area, 61% were youth. This suggests that those who are potentially vulnerable to deterioration in metabolic control constitute more than half of the young CDBH population with type 1 diabetes.

Diabetes control, as measured by HbA1c, was investigated in the Canterbury region at a population level. Lunt et al. (2002) reported HbA1c results for the CDHB population of adolescents and youth (13-20 years old) with type 1 diabetes,  $N = 118$ . These individuals had diabetes of at least one year's duration (referred to as established diabetes), and were identified from a clinical database of the Christchurch Diabetes Centre, which services the CDHB catchment area. The identified list was rechecked using an independent population-based research register; the reported data represented the entire diabetic population in Canterbury for the target age range. The overall average HbA1c was higher than the recommended target, falling in the poor glycaemic control category, which is associated with a higher risk for developing long-term diabetes complications. Females (mean HbA1c = 10.2%) had significantly worse diabetes control than males (mean HbA1c = 9.5%),  $p = 0.042$ . The study recommended that effective ways of delivering young adults diabetes services in Canterbury and New Zealand be explored (Lunt et al., 2002).

A further study was conducted to evaluate diabetes control at a population level in Canterbury, following changes in the delivery of diabetes health services,

between 2001 and 2005 (Lunt, Kendall, Moore, Soule, & Cole, 2006). Changes to the delivery of health services included: designating a minimum of four specialist visits per annum for those aged 13-18 years old (e.g., specialist doctors and nurse visits), forming links between the clinic and the community through a diabetes youth field worker with nursing qualification, scheduling a weekly meeting for the multidisciplinary team staff, assigning case management for selected patients, providing funded insulin treatment for selected patients, and putting greater emphasis on carbohydrates counting (Lunt et al., 2006). These changes were in addition to the services already in place in 2001, such as the inclusion of clinical psychology services and blood glucose meter downloading at the Diabetes Centre.

The data comprised HbA1c results recorded in 2001 ( $N = 119$ ), 2003 ( $N = 147$ ), and 2005 ( $N = 142$ ) for youth residing in the CDHB catchment area who had diabetes for more than a year (Lunt et al., 2006). The mean HbA1c was 9.8%, 9.8%, and 9.1%; respectively, for the years 2001, 2003, and 2005. There was no change in HbA1c from 2001 to 2003, and only in 2001 did females have significantly higher HbA1c ( $p = 0.035$ ) than males. A statistically significant improvement ( $p = 0.03$ ) in HbA1c was observed from the year 2001 to 2005. The overall results, however, still showed higher mean HbA1c levels than the recommended level (i.e.,  $>55$  mmol/mol). In 2005, only 12% of patients achieved the recommended HbA1c target. Thus, despite implementing changes to the diabetes services that aimed to improve glycaemic control that followed on from the findings of the 2001 audit (Lunt et al., 2002), only small changes were observed in diabetes control from 2001 to 2005 (Lunt et al., 2006). The results also suggested that mean HbA1c levels remained mostly in the suboptimal to poor diabetes control category.

Since these studies, there have been no further studies of the prevalence and diabetes control of youth with type 1 diabetes in Canterbury. Thus there is a seven year gap in knowledge, which is critical because it could be used to inform the planning and delivery of diabetes health services to youth with type 1 diabetes. Given the significant short and long term consequences of poorly controlled type 1 diabetes, it is imperative that there is regular ongoing evaluation of the prevalence and diabetes control of youth with type 1 diabetes. The following aims were formulated as part of the current study to bridge some of the gaps in knowledge and to provide up-to-date information which can inform health service providers:

- a) Describe the demographics of youth (15-24 year olds) with type 1 diabetes in the CDHB catchment area and to compare this data with previous research (Wu et al., 2005).
- b) Estimate the prevalence of youth with type 1 diabetes in the CDHB catchment area.
- c) Investigate whether there has been an increase in the prevalence of youth with type 1 diabetes residing within the CDHB catchment area.
- d) Describe diabetes control outcomes and its classifications according to the HbA1c targets of NZSSD (2009b).
- e) Investigate whether there has been any change in diabetes control, as measured by the mean value of HbA1c, from 2001 (Lunt et al., 2002) to 2010 for youth (aged 15 to 20 years) who reside in the CDHB catchment area, and for whom data are available.

Based on the previous research, it was hypothesised that the majority of youth with type 1 diabetes residing in the CDHB would be of European descent, with males

out numbering females. It was also hypothesised that there would be an observed increase in the prevalence of type 1 diabetes in youth. Furthermore it was hypothesised that the diabetes control, as measured by HbA1c, would have improved at a population level from 2001 to 2010, but that the mean HbA1c would still not be within the healthy range (i.e., less than 55 mmol/mol).

## **Method**

The study comprised two main parts that describe and investigate changes in prevalence and diabetes control. The following outlines the procedures for data collection, prevalence estimation, and diabetes control assessment.

The information was collated for youth with type 1 diabetes aged between 15 and 24 years, who resided within the CDHB catchment area. This included Christchurch, the town of Ashburton, and Northern rural Canterbury. The current study identified youth residing in the CDHB catchment area based on an anchor date of 1 November 2010. This date was chosen to align with the previous study's anchor date, 1 November 2003, which yielded a seven-year gap between the two studies (Wu et al., 2005). The search and inclusion criteria (i.e., valid entries) used in the earlier study by Wu et al. (2005) were followed. Thus, those newly diagnosed diabetes and with secondary or type 2 diabetes were excluded from the study – only entries of youth with established type 1 diabetes were included.

The CDHB records were searched in multiple electronic and physical sources. The electronic data sources included the CDHB inpatient and outpatient lists, the Diabetes Youth Canterbury database, and records from the previous study (Wu et al., 2005). The data collected comprised descriptive information and

demographic characteristics of the youth. This included gender, ethnicity, age, residential area deprivation level, diabetes duration, and the most recent HbA1c record. Age data were divided into two age bands (15-19 years and 20-24 years), which represented adolescents and young adults. This division was consistent with the census age categories obtained from Statistics New Zealand (the New Zealand's national statistical department) and allowed comparison with Wu et al. (2005). Missing data-point entries were updated by searching the physical files held at the CDHB Diabetes Centre based on the National Health Index (NHI), and contacting the individual youth's GP. The collated data were entered in raw format and then analysed using Microsoft Excel 2007 and IBM Statistical Package for Social Sciences (IBM SPSS 19).

## **Prevalence**

The prevalence of youth with type 1 diabetes was estimated, and then this was compared to the results of the previous audit conducted in the CDHB in 2003, by Wu et al. (2005). In the current research, the prevalence calculation was based on the 2006 census data (Statistics New Zealand, 2007), whereas the 2003 prevalence calculation was based on the 2001 census data (Wu et al., 2005). Prior to comparing the results of the two studies, the studies populations were checked for adequate comparability. This is because of changes made to some aspects of the 2006 census in comparison to the 2001 census, and two main issues were considered that were of relevance to the current study. The first issue was to base the prevalence calculation on populations drawn from the same source. This was ensured by using the same source from the Statistics New Zealand records to find the total number of the target population residing in the CDHB for each of the years 2001 and 2006; these were

drawn from statistics specific to DHBs (Statistics New Zealand, 2002, 2007). The second issue was related to a difference in the data collection and classification of ethnicity in 2001 compared to the 2006 census. For example, in the 2001 census data the *New Zealander* entry was grouped with the *European* entry; however, in 2006 a separate classification under *other ethnicities* was created to include the New Zealander entries. This issue was remedied by adding the total number of the New Zealander subcategory in the 2006 census data to the total number of the European category, thus making the 2001 and 2006 census population totals comparable to each other.

A further consideration was taken into account in comparing the estimated prevalence over time, which was to eliminate a potential confounding effect from different population compositions (Boniol & Heanue, 2007; Boyle & Parkin, 1991; Naing, 2000). Changes in prevalence from 2003 to 2010 were assessed using standardised prevalence rather than crude prevalence. *Crude prevalence* presents a measure of the entire population and does not account for the composition of subgroups within that population, whereas *standardised prevalence* eliminates the influence of the different makeup of subgroups when comparing prevalences from two populations (Boniol & Heanue, 2007; Boyle & Parkin, 1991; Naing, 2000).

The standardisation procedure is as follows, and in Appendix 2.1 are the relevant equations. Age-specific prevalence in each year was calculated based on the number of observed cases in the total population in each age stratum (Statistics New Zealand, 2002, 2007). Age-standardised prevalence was then estimated by calculating weighted averages of the age-specific prevalence, using 2010 as a reference year. This was to account for differences in population compositions from

2003 to 2010 and to provide a reliable estimate for evaluating change in prevalence over time (Boniol & Heanue, 2007; Boyle & Parkin, 1991).

The change in prevalence was statistically evaluated by calculating an age-standardised prevalence ratio (ASPR), also referred to as a standardised morbidity ratio (SMR), which is the ratio of the 2010 age-standardised prevalence to that of the year 2003 (Boniol & Heanue, 2007; Boyle & Parkin, 1991). The 95% confidence interval (CI) was calculated to assess whether there was a statistically significant difference between the prevalence from 2003 to 2010. A statistically significant difference is said to exist if the ASPR is significantly different from unity (i.e., the CI does not include one), which is equivalent to zero in a standard 95% CI of the difference between means (Boniol & Heanue, 2007; Boyle & Parkin, 1991).

### **Diabetes control**

In the second part of the audit study, the data collected above were used to describe the population of youth with type 1 diabetes in terms of their diabetes control, as measured by HbA1c. This included finding the percentage of people with particular HbA1c levels in each category of diabetes control classifications (e.g., excellent, acceptable, and poor), and the category of diabetes control for the overall mean. A comparison of current diabetes control with the study by Lunt et al. (2002) was conducted. It is of note, however, that the age range in the earlier study was 13 to 20 years old, which did not match the age range for the current study and therefore, a sub-group (15-20 years old) was used to compare matching groups' results for the designated years.

An independent-samples t-test was carried out assuming that the variability in



2001 was the same as that observed in 2010, because no variability measures were reported in the 2001 audit (Lunt et al., 2002). The 2001 audit reported the number of youth entries, and HbA1c mean values, but did not report the *SD* for the population HbA1c. In order for the two groups to be compared using a t-test requires a mean, *SD*, and a total number of entries for each of the groups; the same *SD*, obtained from the current study, was assumed for both groups. The aim of the comparison, as previously mentioned, was to investigate if there had been any change in diabetes control, as measured by the mean value of HbA1c, from 2001 to 2010 for youth (aged 15 to 20 years) residing in the CDHB catchment area. An independent-samples t-test was also used to identify whether in 2010 there was a statistically significant difference in mean HbA1c values between females and males. This was explored because there had been a significant difference in diabetes control between females and males in the 2001 study (Lunt et al., 2002).

## **Results**

### **Prevalence**

The number of youth with type 1 diabetes residing within the CDHB catchment area on the anchor date 1 November 2010 was 248. The demographics of these youth are depicted in Table 2.1.

**Table 2.1**

*Demographics of youth with type 1 diabetes, who are residing within the CDHB catchment area in 2010*

		<i>n</i>	%
Gender	Female	120	48.4%
	Male	128	51.6%
Age Groups* (years)	(15-19)	131	52.8%
	(20-24)	117	47.2%
Ethnicity	European	227	91.5%
	Maori	9	3.6%
	Pacific Peoples	3	1.2%
	Other	9	3.6%
Diabetes duration** (years)	between 1 and 5	55	22.2%
	between 6 and 10	82	33.1%
	between 11 and 15	68	27.4%
	between 16 and 20	33	13.3%
	more than 20	10	4.0%
Deprivation quintiles***	1	77	31.2%
1= least deprived area	2	55	22.3%
	3	55	22.3%
	4	35	14.2%
	5	25	10.1%

*Note.*

\* Mean age was 19.2 years old (*SD* = 2.6 years);

\*\* Mean length of diagnosis was 10 years (*SD* = 5.4 years; minimum = 0.9 year (11 months); maximum = 22 years);

\*\*\* (Statistics New Zealand, 2011).

The percentage of females and males were 48.4% ( $n = 120$ ) and 51.6%, ( $n = 128$ ) respectively. The majority (91.5%;  $n = 227$ ) of youth with type 1 diabetes were European New Zealanders. The percentage of 15-19 year olds (adolescents) was 52.8% ( $n = 131$ ), and 20-24 year olds (young adults) was 47.2% ( $n = 117$ ). The diabetes' duration ranged from 11 months to 22 years, with one third (33.1%) in the

6-10 year duration range. About a third (31.2%) of youth with type 1 diabetes resided in the least deprived socioeconomic area (quintile 1).

Based on the total number of youth with type 1 diabetes residing within the CDHB catchment area in 2010, the prevalence was calculated using the 2006 census data. The majority (91.5%;  $n = 227$ ) of youth with type 1 in Canterbury were European new Zealanders and data in this ethnic group were stratified by age. The two age bands were 15-19 years and 20-24 years, which correspond to the census age categories, and were also presented in the previous audit (Wu et al., 2005). The results are depicted in Table 2.2, which shows age-specific and age-standardised prevalences for both 2010 and 2003 (Wu et al., 2005). Table 2.3 shows the percentage of changes from 2003 to 2010 in the number of cases and prevalence of youth with type 1 diabetes, and the general youth population.

**Table 2.2**

*Prevalence of European New Zealanders with type 1 diabetes (stratified by age) residing in the CDHB catchment area in 2010 and 2003*

Year		15-19 years	20-24 year	% of difference	ASP <sup>+</sup>
2010	Cases	126	101	22.0	
	Prevalence per 100,000	443	406	8.7	426
	(95% CI)	(366 to 520)	(327 to 485)	-	(370 to 481)
	Population*	28,452	24,891	13.4	
2003	Cases **	92	95	3.2	
	Prevalence per 100,000	369	394	6.6	380
	(95% CI)	(294 to 444)	(315 to 473)	-	(326 to 435)
	Population ***	24,951	24,126	3.4	

*Note.* <sup>+</sup> Age-standardised prevalence;

\* (Statistics New Zealand, 2007);

\*\* (Wu et al., 2005);

\*\*\* (Statistics New Zealand, 2002).

**Table 2.3**

*Percentages of increase from 2003 to 2010 in the cases and prevalence of European New Zealanders with type 1 diabetes, and the general population*

	15-19 years	20-24 years
Cases with type 1 diabetes	37.0%	6.3%
Prevalence of type 1 diabetes	20.0%	3.0%
General youth population *	14.0%	3.2%

*Note.* \* Inclusive of all youth with or without diabetes

The age-specific data shows that there had been an increase in the number of the adolescents and young adults with type 1 diabetes over time (Table 2.2-3), with a 37% and 6.3% increase in the crude number of cases, respectively. There was a prevalence increase of 74 per 100,000 (20%) in adolescents (15-19 year olds), and 12 per 100,000 (3%) in young adults (20-24 year olds) with type 1 diabetes. These age-specific increases, however, were not statistically significant in each age group.

The age-standardised prevalence per 100,000 was estimated by calculating the weighted average of the age-specific prevalence using the year 2010 as a reference year (see Appendix 2.1). From 2003 to 2010 there was an increase of 46 per 100,000 (12%) in the age-standardised prevalence. The ratio of the 2010 to 2003 age-standardised prevalence was used to calculate the ASPR. The ASPR was found to be 1.19 (95% CI: 0.910 to 1.429). The CI includes figure one, which indicates that the difference in prevalence over time was not statistically significant.

In Table 2.3 it can also be seen that there was an increase in the general population of youth from 2003 to 2010, which may have contributed to inflation in the crude diabetes prevalence in 2010. In the adolescents' age band there was an increase of 14%, whereas there was only a 3.2% increase in the general young adult

total population. In addition, the number of adolescents (15-19 year olds) with type 1 diabetes exceeded the number of young adults (20-24 year olds) with type 1 diabetes by 22% in 2010 (Table 2.2). This is in contrast to the findings of the Wu et al. (2005) study, where the number of young adults with type 1 diabetes was slightly (3.2%) larger.

## Diabetes Control

The overall mean HbA1c was 82 mmol/mol ( $SD = 22$  mmol/mol), which fell into the category of poor diabetes control. The majority of youth (93.2%;  $n = 229$ ) had HbA1c levels that exceeded the recommended range (i.e.,  $> 55$  mmol/mol), with more than half of this percentage falling in the poor to extremely poor diabetes control. The observed classifications (Table 2.4) suggest that the majority (77%;  $n = 190$ ) of individuals with type 1 diabetes in Canterbury may require more intensive treatment, with nearly a third requiring urgent interventions or immediate action (NZSSD, 2009b).

**Table 2.4**

*Mean HbA1c and diabetes control range for youth (15-24 year olds) with type 1 diabetes in the CDHB catchment area in 2010*

Range <sup>+</sup>	<i>n</i>	%	HbA1c (mmol/mol)			
			<i>M</i>	<i>SD</i>	Minimum	Maximum
< 50	7	2.8%	41	4	34	45
50-54	10	4.1%	52	1	50	54
55-64	39	15.9%	60	3	55	64
65-79	72	29.3%	72	5	65	79
80-99	59	24.0%	88	5	80	99
>100	59	24.0%	114	13	100	146

*Note.* <sup>+</sup>NZSSD (2009) diabetes control range

The data of the current study for the age range 15-20, Table 2.5, were compared to that of the 2001 audit, Table 2.6 (Lunt et al., 2002). The t-test showed no statistically significant difference ( $p = 0.75$ ) between the two results. The mean HbA1c had neither significantly deteriorated, nor improved since 2001. The mean HbA1c in 2010 was 85 mmol/mol. This exceeded the recommended HbA1c target, and fell in the poor diabetes control category, suggesting that more intensive intervention was required. The gender specific data analysis showed that in 2010 (as it had been in 2001) females had statistically significantly worse ( $p = 0.04$ ) diabetes control than males, with a mean HbA1c 88 and 81 mmol/mol, respectively.

**Table 2.5**

*Mean HbA1c according to gender and age for youth (15-20 years) with type 1 diabetes residing in the CDHB catchment area in 2010*

Age (years)	Female		Male	
	<i>n</i>	HbA1c mmol/mol	<i>n</i>	HbA1c mmol/mol
		<i>M (SD)</i>		<i>M (SD)</i>
15	16	88 (21)	10	74 (18)
16	15	81(23)	13	76(15)
17	11	87(29)	10	84(15)
18	7	104(28)	17	88(27)
19	18	89(19)	14	77(18)
20	11	85(24)	15	87(20)
Total	78	88(23)	79	81(19)
<i>M HbA1c (N=157) = 85 mmol/mol; SD = 22 mmol/mol</i>				

**Table 2.6**

*Mean HbA1c according to gender and age for youth (15-20 years) with type 1 diabetes residing in the CDHB catchment area in 2001 (Lunt et al., 2002)*

Age(years)	Female		Male	
	<i>n</i>	HbA1c (mmol/mol)	<i>n</i>	HbA1c(mmol/mol)
		<i>M</i>		<i>M</i>
15	5	76	5	73
16	9	96	10	83
17	7	101	8	87
18	9	86	7	80
19	7	88	12	83
20	5	81	7	64
Total	42	88	49	78
<i>M HbA1c (N = 91) = 83 mmol/mol, SD was not reported</i>				

## Discussion

Type 1 diabetes is a chronic illness that is associated with multiple challenges. In addition to the individual's diabetes-management challenges, there are challenges for the health system. These include the planning and accessibility of resources, such as medication, equipment, and access to appropriately trained health care professionals (International Diabetes Federation, 2013; Ministry of Health, 2014). Additional health costs stem from long-term complications, such as kidney failure and nerve damage that are associated with poorly controlled type 1 diabetes (Donaghue et al., 2009; International Diabetes Federation, 2013; Wilson & Sharma, 1995). The burden on the health system is likely to be greater if these long-term complications arise at an early age (Ministry of Health, 2014). As a consequence, it is important for health care planners to gather data on the demographics, prevalence and trends of diabetes in specific populations, and in particular for the youth population for whom diabetes management can pose significant challenges (Ministry of Health, 2014).

The current study gathered these data for youth (15-24 year olds) with type 1 diabetes residing within the CDHB catchment area. The results indicate that the majority of youth with type 1 diabetes in the CDHB catchment area are European New Zealanders, with males slightly out numbering females. These results are similar to the previous study by Wu et al., (2005) but in the current study the number of adolescents with type 1 diabetes exceeded that of young adults. This is in contrast to the findings of Wu et al., (2005) who found the opposite (Table 2.2).

The difference in findings between the two studies may be because of the



difference in the total number of the general youth population in each age band (see Table 2.3). An increased number in the general population of adolescents compared to that of young adults may suggest the likelihood of more presentations of youth with type 1 diabetes. Of note is that the difference in the total population compositions constitutes a confounding factor that may affect evaluating change in prevalence over time if analyses are only based on crude prevalences. However, the age-standardisation used in the current study increases the reliability of results in accounting for this factor because the ASPR reliably estimates the change in prevalence (Boniol & Heanue, 2007).

The age-standardised prevalence of youth with type 1 diabetes had increased by 46 per 100,000 (12%) from the previous audit (Wu et al., 2005), but, based on the ASPR results, this was not statistically significant. This finding is similar to the results of an earlier study of 15 to 19 years old with type 1 diabetes in the CDHB catchment area which similarly did not find a statistically significant increase over time (Willis et al., 2002). In comparison to the Wu et al. (2005) results, the age-specific prevalence in the current study was greater in each age band (Table 2.3), but this was not statistically significant. The increase in the prevalence of adolescents with type 1 diabetes was greater than that of young adults. Again, as explained above, this increase could be expected given the increase in the general adolescent population from the 2001 to 2006 in comparison to that in the general young adult population (see Table 2.3).

The results also indicated that a high percentage of youth with type 1 diabetes in the CDHB catchment area resided in the least deprived socioeconomic areas (53.5% in deprivation quintiles 1 and 2). This result may simply be representative of

the wider Canterbury population, that is, youth of European descent in Canterbury (which includes most of the cases of youth with type 1 diabetes in this region) may be more likely, in general, to reside in least deprived socioeconomic areas (Maré, Mawson, & Timmins, 2001). It was not possible to determine if this is a statistically significant result. This would have required: an estimated prevalence of the CDHB youth residing in the different deprivation quintiles; and the linking of residential mesh blocks to the different socioeconomic deprivation levels in the CDHB area and to the target youth age ranges. These were not possible in the current study due to time constraints. It is therefore, recommended that future research explores this aspect in greater depth.

It should be noted that the present study may not have identified all youth with type 1 diabetes within the CDHB catchment area and there may be missing entries. Capture-recapture was applied in the present study, using the previous study records (Wu et al., 2005), but potentially missing entries could have been cross-checked by using an additional capture-recapture method. This could have included setting a search date of two to three years back to check hospital records more extensively, rather than only checking records one year back. It is expected that youth with diabetes have a medical examination at least once a year. Records may be missed if they had not attended their annual check-up in 2010, or have not been admitted to the hospital during that time. More entries may have been captured, if the search period was extended to, for example, two years back from the anchor date.

Although the aforementioned limitations may have resulted in missing entries, this number is believed to have been minimised because multiple sources were checked for youth entries, including youth databases, inpatient and outpatient

records, and records of patients who had been discharged from hospital. Furthermore, the composition of demographic factors for youth with type 1 diabetes in the present study (i.e., 91.5% Europeans, and 48.4% female and 51.6% males), was similar to the total CDHB youth population (Statistics New Zealand, 2007). For instance, according to the 2006 census records, the total population of European youth in the CDHB was 83% and the percentage of males was higher than females. This gives confidence that the results of the current study are an accurate representation of youth with type 1 diabetes in the CDHB catchment area.

Achieving optimal diabetes control is challenging both for individuals with type 1 diabetes, and also for health service providers at a population level (Lunt et al., 2006). In adolescence and young adulthood, there are additional developmental challenges that may have an impact on type 1 diabetes management and control (Borus & Laffel, 2010; Hamilton & Daneman, 2002; Pinhas-Hamiel et al., 2014). The current research found that the overall mean HbA1c of youth (15-24 year olds) with type 1 diabetes in the CDHB catchment area exceeded the recommendation for healthy control, falling into the poor to extremely poor diabetes control category (NZSSD, 2009b). This is despite the implementation of upgraded service strategies (Lunt et al., 2006). This result is similar to the findings from previous audits (Lunt et al., 2002; Lunt et al., 2006). This signals a need for conducting more frequent audits on diabetes control and evaluating and reviewing current services for youth with type 1 diabetes, as well as exploration of additional services, particularly for youth with poorly controlled diabetes.

The results of the current study also showed that females had significantly poorer diabetes control than males. This is similar to earlier findings by Lunt et al.

(2006), and this is also consistent with previous overseas research (e.g., Burke, 2004; Lagreca, Swales, Klemp, Madigan, & Skyler, 1995). Differences observed in diabetes control, on the basis of gender, may be partly attributed to differential psychological, social, and physiological aspects. For young women, these include variations in insulin requirements during the menstrual cycle because of hormonal changes, and also eating disorders, which are more common in females (Glick, 2009; Lagreca et al., 1995). A study by Tosh, Wong, Shen, Zhang, and Orr demonstrated gender-specific correlates of glycaemic control and showed females had worse outcomes than males. The study found that females with type 1 diabetes (aged 12 to 21), compared to males, had poorer quality of life, lower level of self-confidence, poorer level of diabetes management, and more misuse of insulin (e.g., delaying, missing, or altering their insulin doses). These factors may result in there being gender differences in diabetes control, and this creates the need to address unique requirements of each vulnerable group, such as that for females with poor diabetes control.

Although there was a statistically significant improvement in HbA1c from 2001 to 2005 (Lunt et al., 2006), the current study found that overall there was no change from 2001 to 2010. This suggests that diabetes control may have worsened in the period 2005 to 2010. A direct comparison between the results of the current study and Lunt et al. (2006) was not feasible, because of the lack of access to detailed information with regards to the age categories in Lunt et al. (2006). Without further information this result cannot be confirmed.

To conclude, the absolute figures obtained in the present study suggest an increased demand on health care resources in Canterbury associated with youth with

type 1 diabetes compared to seven years ago. It is recommended that the results from the present study be used to inform planning and decision-making related to diabetes health services both in the short term and in the longer term. For example, if youth receive effective health services in the short term, this may delay or prevent the onset of long-term complications, and therefore reduce future health care costs.

The overall mean value of HbA1c suggests that on average youth, who reside in the CDHB catchment area, have poorly controlled diabetes and, therefore, have an increased likelihood of the early onset of diabetes complications. In addition, females had statistically significant poorer diabetes control than males. Furthermore, the population mean HbA1c has not improved since 2001, suggesting that while there has been no deterioration in results for youth with type 1 diabetes in the CDHB area, neither has there been any overall improvement in outcome. Further action to achieve better diabetes control (i.e., lower the mean HbA1c) in youth with type 1 diabetes is therefore recommended.

In addition to medical interventions to improve HbA1c, it is essential to study and understand psychosocial characteristics that influence glycaemic control and diabetes self-management. Research shows that there are several key psychosocial factors that could impact on diabetes control. The next chapter presents a study of psychosocial factors (i.e., self-efficacy, illness perceptions, and quality of life) in relation to HbA1c with youth with type 1 diabetes in Canterbury.

# Chapter 3

## *Psychosocial Evaluation*

*Understanding illness beliefs, self-efficacy, and diabetes quality of life in relation to glycaemic control in youth with type 1 diabetes*

## **CHAPTER 3: PSYCHOSOCIAL EVALUATION**

### **Introduction**

Diabetes is a chronic condition and as such may be considered a burden but with an extra load on youth because they are at a demanding stage developmentally (Delamater, 2000; Delamater et al., 2014). In addition to the increased physiological requirements during this period, there are other factors including psychosocial, cognitive, and emotional factors that may create obstacles to adequate diabetes self-management and influence diabetes outcome (Delamater et al., 2014; Hagger & Orbell, 2003; Kovacs, Goldston, Obrosky, & Bonar, 1997; Wysocki et al., 1992). During the years of emergence from early adolescence to adulthood, in addition to the naturally occurring physical developments, youth acquire and develop their identities, beliefs, and perceptions in the context of their surroundings, but also in relation to any chronic illness they have (Borus & Laffel, 2010; Delamater et al., 2014; Herge et al., 2012). These beliefs and perceptions have been found to impact on diabetes control and self-management behaviour (Delamater et al., 2014; Mc Sharry, Moss-Morris, & Kendrick, 2011; National Collaborating Centre for Women's and Children's Health, 2004; Skinner, John, & Hampson, 2000).

Poorly controlled diabetes has been found to be associated with low self-efficacy, emotional distress, poor quality of life (QoL), depression, anxiety, poor communication in relation to diabetes, and negative coping and adjustment strategies (Delamater et al., 2014; Fogel & Weissberg-Benchell, 2010; Scholes et al., 2013). Although there has been extensive research that explores a number of influencing factors, there are still gaps in knowledge particularly for the youth developmental

stage, including research on the role of particular psychosocial factors (e.g., illness perception) in predicting diabetes control (Delamater et al., 2014). Further research on psychosocial determinants and barriers, and how they relate to aspects of diabetes management may provide further guidance to help youth who are struggling with their diabetes management.

The current study is concerned with three main psychosocial constructs that have been found to be associated with diabetes management, particularly in relation to glycaemic control (measured by HbA1c) and diabetes self-control (e.g., Hanna et al., 2013; Harvey & Lawson, 2009; Kristensen, Birkebaek, Mose, Hohwu, & Thastum, 2014; Nansel, Weisberg-Benchell, Wysocki, Laffel, & Anderson, 2008; Nardi et al., 2008; Puri, Sapra, & Jain, 2013; van der Ven et al., 2003; Xiong et al., 2013). The main constructs are illness perception, self-efficacy, and diabetes-related QoL. These constructs encompass several dimensions that include cognitive, emotional, physical, behavioural, and social well-being. The current study has two broad objectives: to describe key psychosocial characteristics of youth (15-24 years old) with type 1 diabetes in the CDHB catchment area; and to explore the relationship between these psychosocial characteristics and glycaemic control. The review that follows outlines the relevant literature related to the above objectives and this is followed by the specific aims, hypotheses, and contributions of this thesis. This chapter also describes the methodological basis related to the participants, measures, and data collection, entry and analysis. This research in this chapter has been presented at the Australasian Society for Behavioural Health and Medicine (ASBHM) 12th Annual Scientific Conference, and at the NZSSD 37th Annual Scientific Meeting (Obaid, Britt, Basu, & Wallace-Bell, 2013, 2014).



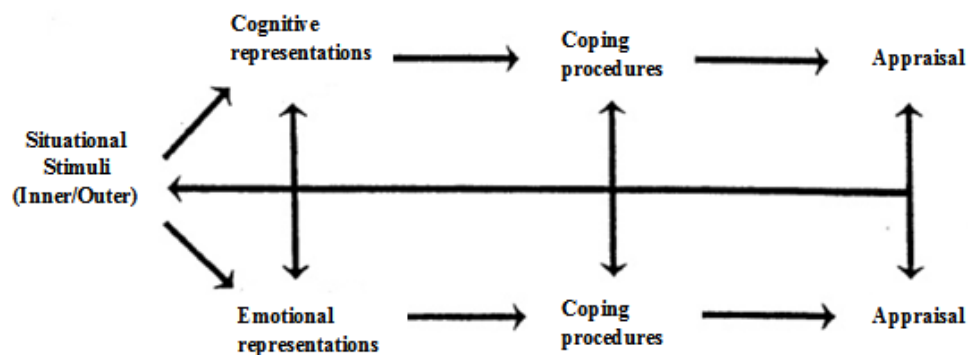
## **Illness Perceptions**

An individual with a health issue develops perceptions that guide and have an impact on the management and clinical outcomes of their condition (Fortenberry et al., 2014; Hagger & Orbell, 2003; Weinman & Petrie, 1997). Illness perceptions emerge through one's experiences and exposure to different elements associated with an illness (or a health threat), including the daily management of the condition, communication with health care professionals, and interaction with family members and peers (Leventhal et al., 1997; Petrie, Jago, & Devcich, 2007; Weinman & Petrie, 1997).

Individuals develop coping strategies to address a health threat, and these can include seeking professional advice, using medication as prescribed, expressing emotion, and avoidance or denial (Luyckx, Vanhalst, Seiffge-Krenke, & Weets, 2010). Reactions towards a health condition and strategies to cope with it can be drawn from interpretations of the different elements (e.g., physical and psychosocial factors) linked to the condition, which lead to the individual creating representations of that illness (Diefenbach & Leventhal, 1996; Petrie et al., 2007). Illness representations are an individual's "implicit common sense beliefs about their illness" (Harvey & Lawson, 2009, p. 7).

Illness representations are central to the Self-Regulation Model (SRM), which follows a dynamic cycle comprising: forming views and beliefs about a health threat, developing coping strategies and engaging in corresponding physical or mental behaviours, and evaluating the current health state and re-assessing inputs from perceptions and coping strategies (Diefenbach & Leventhal, 1996; Leventhal;

Leventhal et al., 1997; Leventhal, Diefenbach, & Leventhal, 1992). In the appraisal phase the illness perceptions and coping actions may be altered. There are two parallel processes in this cycle, which correspond to cognitive and emotional representations generated from both internal and external situational stimuli in response to a health threat. The processes and parallel paths are depicted in Figure 3.1 (Leventhal et al., 1997).



**Figure 3.1.** Illness representations cycle described in a parallel response model, which has (based on the generated response) two interactive paths of cognitive and emotional representations (Leventhal et al., 1997).

Emotional representations reflect emotional reactions that form an adaptation towards an illness, which could lead either to constructive or to maladaptive coping strategies (Diefenbach & Leventhal, 1996). Emotional representations include expressing emotions such as concern, anger, fear, and anxiety, or conversely, seeking emotions, such as reassurance (Diefenbach & Leventhal, 1996). Emotionally driven coping strategies, such as denial, avoidance, suppression, or venting may also contribute to the emotional representations (Diefenbach & Leventhal, 1996; Leventhal et al., 1997).

Cognitive representations include five core dimensions: *identity*, which reflects beliefs about attribution of symptoms to an illness and associating labels with those symptoms; *consequences*, which represent beliefs on the impact of the illness and its expected outcomes (e.g., seriousness of a condition and vulnerability to develop complications); *timeline*, which reflects the period for which the illness is going to last (e.g., acute, episodic, or chronic); *control or cure*, which represent thoughts associated with how much an individual has control over the illness management or recovery from it (i.e., personal control, and treatment control and effectiveness) (Lau & Hartman, 1983); and *cause*, which depicts personal views on causes responsible for the illness or condition (e.g., internal causes including biological factors or external causes including environmental factors) (Hagger & Orbell, 2003; Leventhal et al., 1992). Further research has also identified *coherence* as an additional core dimension, which reflects views associated with the overall understanding of an illness (Weinman, Petrie, Moss-Morris, & Horne, 1996).

Cognitive and emotional illness representations can be evaluated using SRM based measures. These measures include self-report assessment tools, such as the Illness Perceptions Questionnaire (IPQ) and the Brief-IPQ (BIPQ) (Broadbent, Petrie, Main, & Weinman, 2006; Moss-Morris et al., 2002); and semi-structured interviews, such as the Personal Models of Diabetes Interview (PMDI) (Hampson, Glasgow, & Toobert, 1990). All of the SRM based measures were constructed such that higher scores indicate stronger beliefs with regards to the corresponding dimension (Hagger & Orbell, 2003). Stronger beliefs on identity, consequences, timeline, and emotional representations denote negative perceptions. These negative perceptions indicate a highly perceived symptomatic condition, more serious

consequences and impact on life, greater emotional reactions to an illness, and chronic rather than acute views of illnesses. In contrast, higher scores on controllability and coherence depict positive perceptions, which reflect stronger beliefs about the manageability of the illness and recovery from it, and a greater understanding of the illness.

Studies have explored the association between illness representations, and health behaviours and outcomes, but with much of the research focusing on cognitive representations (Broadbent, 2010; Kucukarslan, 2012). Significant associations across studies of various illnesses outcomes and illness representations have been reported (Hagger & Orbell, 2003). A meta-analysis of empirical studies of illness presentations by Hagger and Orbell (2003) found the following key findings: stronger views on identity, consequences, and timeline were associated with increased use of negative coping strategies and emotion expression, and worse physical, psychological, and social well-being. In contrast, stronger views on the controllability dimension (i.e., high degree of perceived control over an illness) were positively associated with constructive coping strategies, and improved psychological and social well-being. In Hagger and Orbell's (2003) meta-analysis, studies of diabetes and illness perceptions constituted the largest illness group (12 studies). Findings from this meta-analysis and later research have demonstrated associations between illness perceptions and diabetes-related variables, including glycaemic control, diabetes self-management behaviours, and physical and psychosocial well-being (Hagger & Orbell, 2003; Harvey & Lawson, 2009). The associations were found across different age groups and for type 1 and type 2 diabetes. Stronger beliefs on controllability and treatment effectiveness across studies

were consistently associated with improved glycaemic control, better adherence to a diabetes regimen, and enhanced QoL (Harvey & Lawson, 2009). In contrast, poorer glycaemic outcomes were correlated with greater emotional reactions towards diabetes, more concern, higher level of identity perceptions, and cyclical or unpredictable timeline. A higher score on consequences was also associated with poorer outcomes: strong beliefs about diabetes as a threatening disease (i.e., seriousness of diabetes and feelings of vulnerability to the development of complications) were associated with poorer self-management, higher distress levels, and non-attendance at diabetes clinics (Kibbey, Speight, Wong, Smith, & Teede, 2013; Lawson, Bundy, Lyne, & Harvey, 2004; Queralt, 2010). It should also be noted that significant associations between illness perception and HbA1c and diabetes self-management have not always been detected (Klis, Vingerhoets, de Wit, Zandbelt, & Snoek, 2008; McGrady, Peugh, & Hood, 2014; Nouwen, Law, Hussain, McGovern, & Napier, 2009; Queralt, 2010).

The above provides an overview of illness perceptions and in relation to diabetes; a more specific and detailed literature review specific to youth with type 1 diabetes and illness perceptions follows. Studies that used HbA1c as an outcome measure, which is the primary outcome measure in the present study, are detailed first, then research that investigates illness perceptions using self-report outcome measures is presented.

### **Youth with type 1 diabetes and illness perceptions**

The role of illness perceptions in glycaemic control and adherence to diabetes self-management was investigated among youth (15-25 years) with type 1 diabetes

by Griva, Myers and Newman (2000). Their study examined whether illness perceptions can explain some of the variation in HbA1c, and whether it can predict adherence to diabetes self-management recommendations including SMOBG, insulin use, diet, and exercise, and an overall adherence component (Griva et al., 2000). The study comprised 64 Caucasian youths from London, United Kingdom (UK) who were attending two diabetes clinics. The mean HbA1c in this sample was 8.7% ( $SD = 1.4\%$ ). Illness perception beliefs were assessed using the IPQ, which is focused on cognitive representations (identity, timelines, consequences, and control) and does not address the emotional representations of SRM. An initial examination of groupings based on gender and age (15-19 years old, and 20-24 years old) revealed no significant differences in the variables between females and males, or the age bands, and therefore, the combined group was included for further analyses.

Zero-order correlations among domains of illness perception, metabolic control and adherence showed several significant associations; additionally interrelationships of IPQ components had significant correlations. On the IPQ dimensions, perceived seriousness of consequences was positively associated with strength of illness identity ( $r = 0.41, p < 0.001$ ) and negatively associated with control beliefs ( $r = -0.29, p < 0.01$ ). Illness identity perceptions were also negatively associated with the latter ( $r = -0.31, p < 0.01$ ). Lower HbA1c (better glycaemic control) was significantly associated with positive perceptions of identity, consequences, and controllability ( $r = 0.31, r = 0.23, r = -0.35$ , respectively,  $p < 0.01$ ). Perceived diabetes control was positively associated with all adherence components. Participants who had higher perceived control had better adherence to SMOBG, insulin, dietary, and exercise recommendations ( $t(62) = 7.80, p < 0.001$ ;

$t(62) = 2.79, p = 0.007$ ;  $t(62) = 3.25, p = 0.002$ ;  $t(62) = 2.82, p < 0.006$ ; respectively), compared to those in the poor adherence group. Participants with negative identity perceptions (more attribution of symptoms to diabetes) reported poor adherence to SMOBG ( $t(62) = -2.68, p < 0.009$ ), dietary adherence and poor overall adherence ( $t(62) = -2.74, p < 0.000$ ), compared to those in the good adherence group. The consequences and timeline did not have significant associations with any of the adherence components.

Hierarchical multiple regression analysis of the role of illness beliefs in predicting HbA1c demonstrated significant contributions from two illness perception components: perceived consequences and identity ( $\Delta R^2 = 5.7\%$  and  $6.5\%$  respectively), with the total proportion of contribution accounting for a  $12.2\%$  of the variance in HbA1c levels. On overall adherence, perceived control was the only significant predictor accounting for more than third ( $39\%$ ) of the variance of the total adherence. In summary, the above study provided empirical evidence of the role of illness perceptions in glycaemic control and adherence. The findings suggest the potential usefulness of illness perception beliefs as predictors of adherence and metabolic control for youth (15-25 years) with type 1 diabetes. An analysis of the emotional representation component, however, was not provided because the IPQ focuses on cognitive representations.

Pereira, Almeida, Rocha, and Leandro (2011) investigated the relationship between several psychological variables, including illness perceptions (measured by BIPQ), adherence, QoL, and HbA1c. The study recruited 85 children and adolescents (12-19 years old) with type 1 diabetes from two central hospitals in Portugal and clinics run by the Diabetic Association of Portugal. The mean HbA1c in the sample

was 9.1% ( $SD = 1.6\%$ ). Multiple hierarchical regression analyses revealed that participants' emotional representation predicted metabolic control and QoL ( $beta = 0.356, p < 0.001$ ;  $beta = 0.254, p < 0.05$ , respectively). Greater perception of diabetes as a threatening disease (i.e., emotional representation) predicted higher HbA1c and poorer diabetes-related QoL. Adherence to recommendations of self-management behaviours was predicted by the personal control illness representation ( $beta = -0.364, p < 0.001$ ), with lower perception of personal control predicting lower adherence. Higher perceived consequences was associated with poorer QoL ( $beta = 0.284, p < 0.05$ ).

The Pereira et al. (2011) study provides evidence for the effect of the illness representations on metabolic control, adherence, and QoL. This study used hierarchical regression analyses, which provided confirmatory analysis of the relationships amongst the study variables. However, it did not control for age in the regression models; the age range included both children and adolescents.

Illness representations in youth (15-20 years) with type 1 diabetes were examined in relation to predicting glycaemic control, frequency of SMOBG (downloaded from meter), and adherence to diabetes self-management recommendations (McGrady, 2012; McGrady et al., 2014). The participating youth ( $N = 99$ ) were recruited from a hospital in the mid-western United States of America (USA). Data were collected at two time points that were about 18 weeks apart: Time 1 and Time 2. The data included scores from the Diabetes Illness Representation Questionnaire (DIRQ), HbA1c, self-reported diabetes self-management behaviours, as well as the self-reported and meter downloaded frequency of SMOBG. The mean HbA1c at Time 1 ( $N = 96$ ) was 8.96% and at Time 2 ( $N = 88$ ) was 8.69%. The



HbA1c and illness perception had mostly no significant correlation at either Time 1 or Time 2, except at Time 1 on the coherence ( $r = -0.22, p < 0.05$ ) and treatment control ( $r = -0.31, p < 0.01$ ) scales. There were several significant associations between illness perceptions and adherence and frequency of SMOBG at both time points; for example, stronger perceived treatment effectiveness was positively correlated with more frequent SMOBG ( $r = 0.25, p < 0.01$ ).

The regression analyses in the hierarchical and structural equation models presented a confirmatory evidence for the significant associations; the models controlled for age and gender. The Time 1 model revealed that illness representations accounted for 23% ( $p < 0.01$ ) of the variance in self-reported frequency of SMOBG and 7% of the variance in adherence to emergency precautions ( $p < 0.05$ ); the remaining variables including HbA1c had non-significant associations. The Time 2 model presented evidence of the following relationships: illness representations ( $p < 0.05$ ) accounted for an 8% of the variance in self-reported blood glucose monitoring, 8% in adherence to recommendations for insulin use and diet and 10% in exercise, and 16% in adherence to emergency precautions. McGrady (2012) also examined mediational models and found that the frequency of SMOBG and adherence were two of the variables that mediated the relationships between perceived timeline, understanding, and consequences illness representations and metabolic control.

In summary, the study by McGrady (2012) presented evidence for the role of illness perceptions in diabetes self-management behaviours for youth (15-20 years) with type 1 diabetes, but there was no evidence supporting the hypothesis that illness perceptions have a direct role in predicting metabolic control. Not detecting an association, however, does not imply a correlation was non-existent, further

investigations are required to determine that. The study did, however, demonstrate the indirect effect of illness perception, through diabetes self-management behaviour (including the frequency of SMOBG), on HbA1c.

A longitudinal study by Fortenberry et al. (2014) examined illness perceptions in children and adolescents (10-17 year olds) with type 1 diabetes. The study investigated the illness perceptions (measured by IPQ-Revised) over time, and in relation to HbA1c, adherence, and QoL. The study participants ( $N = 213$ ) were recruited from a university/private partnership clinic and a community-based private practice, California, USA. This study was part of a larger study that followed participants with type 1 diabetes aged 10-14 years for 2.5 years, and had 6-month follow-up intervals. A series of multilevel models were used to examine longitudinal trajectories of illness perception in the participants over time, and also examined the relationship between illness perceptions and diabetes outcomes.

Results indicated that illness perceptions changed over time and showed significant ( $p < 0.01$ ) positive slopes for chronicity, consequences, personal and treatment control, as well as for coherence. This suggests that over time adolescents perceived their condition with an increased level of chronicity and negative consequences (i.e., more threatening views). Furthermore, as they became older, adolescents had an increased level of perceived personal and treatment control over the illness, and had more understanding of their condition. Results from the multilevel prediction models showed that better HbA1c was significantly ( $p < 0.05$ ) associated with perception of less severe consequences, higher level of coherence and fewer negative emotions. A higher level of adherence was predicted ( $p < 0.05$ ) by greater level of perceived personal control, treatment control, coherence, and

lower negative emotional representations. Finally, better QoL was predicted by lower cyclicalities, consequences, and negative emotional representations; and higher treatment control, and coherence.

The study by Fortenberry et al. (2014) had the strength of longitudinal analysis and it also controlled for factors such as age and gender. The study, however, examined the data at only three time points during the study and this limited establishing more complex models because of the small number of follow up data (Fortenberry et al., 2014).

A study was conducted in Auckland, New Zealand, to assess the psychosocial status of adolescents (11-17 year olds) with type 1 diabetes, and to explore the relationship between psychosocial factors and glycaemic control (as part of a larger study to develop and evaluate a psychological screening tool) (Huggard, 2009). Psychosocial measures included an assessment of illness perceptions using the BIPQ. The study recruited 112 youth from the Auckland DHB. The mean HbA1c was 8.5% ( $SD = 1.97\%$ ). Preliminary analysis of the sample HA1c determined a cut-off HbA1c to create two groups: HbA1c 10% and above, and HbA1c below 10%. Descriptive correlations and t-test comparisons were used in the Huggard (2009) study. Results on the total BIPQ score representing the overall diabetes illness perception were reported, the individual dimension results were not reported. The study found a statistically significant difference in the overall illness perception between females and males, with the males having less troubling illness beliefs. In addition, HbA1c was significantly and positively correlated with the total illness perception score ( $r = 0.32, p = 0.001$ ). This suggests views on diabetes as a negatively threatening condition were associated with poorer glycaemic control. The two HbA1c categories (i.e.,

10+% and <10%) were compared in relation to the total illness perception score using an independent-samples t-test. Participants in the HbA1c  $\geq 10\%$  (i.e., poor control) group had significantly higher total illness perception scores, indicating they had more negative diabetes-related beliefs, in comparison to those in the HbA1c <10% group.

The study by Huggard (2009) provided an explorative analysis of the relationship between HbA1c and illness perception within a New Zealand context. Nevertheless, this relationship needs further investigation using confirmatory analysis. In addition, including HbA1c as a categorical variable (two groups) may limit full exploration of HbA1c associations with other variables.

An Iranian study by Bazzazian and Besharat (2010) produced similar findings to the Huggard (2009) study. Bazzazian and Besharat (2010) validated a translated version of BIPQ with 300 individuals (aged 18-30 years old) with type 1 diabetes, who were members of the Iranian Diabetes Society. They reported significant association between HbA1c and the majority of the BIPQ dimensions: consequence ( $r = 0.595, p < 0.01$ ), personal control ( $r = -0.638, p < 0.01$ ), identity ( $r = 0.760, p < 0.01$ ), concern ( $r = 0.129, p < 0.05$ ), coherence ( $r = -0.177, p < 0.01$ ), emotional response ( $r = 0.549, p < 0.01$ ). The above two studies provide preliminary evidence for the association of HbA1c with illness perceptions, but the findings need be investigated further using confirmatory analysis.

Another New Zealand study, which was also based in Auckland, investigated associations of illness perceptions with HbA1c and adherence to diabetes self-management behaviour (medication, diet, and exercise) (Broadbent, Donkin, &

Stroh, 2011). The study recruited individuals with type 1 and type 2 diabetes. The inclusion age was 16 years and over, and this therefore included not only youth but also adults. A total of 157 completed the questionnaires, 49 of whom had type 1 diabetes ( $M_{\text{age}} = 43.2$ ,  $SD = 20.6$  years). The study had a combined sample analysis (i.e., type 1 and type 2) in the descriptive part of the analysis, but the regression analysis was conducted on the diabetes types. The analyses were inclusive of all ages and did not differentiate youth from adults. The illness perception measure used in this study was the BIPQ.

The majority (86%) of individuals who were on insulin medication (78 participants), reported adherence to insulin (*adherent all the time* group). Individuals in the good adherence group, in comparison to the less adherent group, reported higher perceived personal control and less threatening views on consequences. In the total sample, 22% reported adherence to diet recommendations and 17% to exercise recommendations. Dietary adherence had significant associations with scores on the BIPQ dimensions. More positive beliefs were associated with: fewer symptoms ( $r = -0.28$ ,  $p < 0.001$ ), lower perceived consequences ( $r = -0.22$ ,  $p < 0.01$ ), higher controllability of personal ( $r = 0.34$ ,  $p < 0.001$ ) and treatment ( $r = 0.20$ ,  $p < 0.05$ ), lower emotional representations ( $r = -0.24$ ,  $p < 0.05$ ), and the belief that diet management could help diabetes ( $r = 0.23$ ,  $p < 0.01$ ). Exercise adherence was significantly associated with perceptions of personal control ( $r = 0.20$ ,  $p < 0.05$ ), illness coherence ( $r = 0.18$ ,  $p < 0.05$ ), and the perception that exercise could help diabetes and also prevent heart problems ( $r = 0.30$ ,  $0.21$ ;  $p < 0.001$ ,  $p < 0.05$ , respectively).

The regression analysis conducted on the type 1 diabetes sample revealed that

insulin adherence explained 24% of the variance in HbA1c, and personal control and identity combined, explained an additional 15%. The model therefore confirmed that higher adherence and perceived personal control were related to better metabolic control, but the single contribution of the perceived control and identity in explaining HbA1c was not presented.

The above study conducted by Broadbent et al. (2011) provided information on the associations of adherence to diabetes management behaviours (medication, diet, and exercise) and HbA1c with the illness perception dimensions. The descriptive analysis on the combined sample provided initial indications of the relationships between variables, while the regression analysis on type 1 diabetes confirmed the contribution of certain illness perceptions in predicting glycaemic control. The latter analysis, however, did not control for age or gender in the model. In addition, although the study included participants from the adolescent, young adults and adult age groups, the average age ( $M = 43.20$ ;  $SD = 20.57$  years) suggests that the participants were mostly adults. Further investigations are required to examine the association of illness perceptions in relation to HbA1c in the youth with type 1 diabetes.

In a qualitative study, conducted in the USA, 14 young people (11-22 years old) were interviewed to identify themes of illness perceptions according to levels of metabolic control (Scholes et al., 2013). Participants were classified into two groups based on their HbA1c, with a cut off 7.5% to differentiate the groups with low and high HbA1c, that is, above or below the recommended HbA1c. The low HbA1c group had a mean of 6.9% ( $SD = 0.59\%$ ) and the high HbA1c group had a mean of 9.8% ( $SD = 1.12\%$ ). A 60-90 minute interview with each young person was

conducted by a paediatric nurse; the interview was open-ended, with participants freely discussing their experiences living with type 1 diabetes. Interview themes were analysed using an inductive analysis method. The identified illness perceptions were: cure, reactions to the initial diagnosis, and self-care attitudes. Differences in the two HbA1c groups with regards to themes of illness perceptions were observed. The high HbA1c group had negative responses and experiences when initially diagnosed. They viewed their diabetes as traumatic and experienced fear and isolation, whereas the low HbA1c group had no negative reactions to the initial diagnosis, and had positive experiences. As for the cure beliefs, the high HbA1c group believed there would be a cure for type 1 diabetes, but the low HbA1c group did not believe a cure exists. Avoidance of self-management of diabetes was a theme in the high HbA1c group; this is in contrast to the low HbA1c, which took responsibility for self-managing their diabetes.

A study in Iran developed and tested a model of adjustment to type 1 diabetes incorporating illness perception beliefs using a BIPQ translated to Farsi (Bazzazian & Besharat, 2010; Bazzazian & Besharat, 2012). A total of 300 youth aged 18-30 year olds participated in this research, recruited from Iranian Diabetes Society in Tehran. The HbA1c average was 7.5%, suggesting that the youth on average had good diabetes control. The hypothesised relationship among the study components, which included illness perception and adjustment, was tested using structural equation modelling. Adjustment to diabetes was represented by a combination of three components: psychological well-being, QoL, and HbA1c.

Bazzazian and Besharat (2012) found that illness perceptions had a positive regression effect on adjustment ( $t\text{-value} = 8.25$ ,  $p < 0.01$ ), suggesting better

adjustment to diabetes can be predicted from positive and less threatening illness perceptions. However, a direct relationship between illness perception and HbA1c was not investigated. This limits conclusions which can be drawn regarding the relationship between illness perception and HbA1c.

There have been other studies that investigated illness perception, but they did not include HbA1c in their analysis. Some excluded HbA1c in the analysis based on the zero-order associations (Nouwen et al., 2009; Queralt, 2010). If HbA1c was not significantly associated with illness perception, then it would be discarded from further analysis. These studies are presented below.

A study by Nouwen et al. (2009) investigated the role of self-efficacy and illness representations in relation to dietary self-management and diabetes distress. Their study recruited 151 adolescents (12-18 years old) with type 1 diabetes from six regional hospitals in the UK; the mean HbA1c was 9.1% ( $SD = 1.9\%$ ). The Nouwen et al. (2009) study did not find a significant association between HbA1c and illness perception dimensions (perceived consequences and treatment effectiveness), and therefore excluded HbA1c from further analysis. Lower level of perceived consequences and stronger beliefs of treatment effectiveness, however, were significantly associated with better dietary self-management and less diabetes distress.

Similarly, an association between HbA1c and illness perceptions was not detected by Queralt (2010). This study had 85 participants aged 12-18 years, recruited from two diabetes clinics in the UK, the mean HbA1c was 9.9% ( $SD = 1.9\%$ ). The purpose of Queralt's (2010) study was to examine self-efficacy and



illness representations in relation to dietary self-management, metabolic control, and diabetes related distress in adolescents with type 1 diabetes. Queralto (2010) found that consequence beliefs, motivation toward dietary self-management activities, and dietary self-efficacy accounted for 36% of the variance in adolescents' distress levels. Lower distress levels were associated with higher levels of self-efficacy, motivation, and lower levels of perceived consequences.

Other studies that did not include a glucose measure reported a mix of significant and non-significant relationships of illness perceptions with other diabetes-related variables. A study by Law, Kelly, Huey, and Summerbell (2002), which recruited 30 adolescents (aged 13-19 years old) with type 1 diabetes, investigated illness perceptions in association with self-management behaviours and psychosocial factors. The participants were recruited from northeast England and had a mean HbA1c of 9.1% ( $SD = 1.4\%$ ). The authors found that illness beliefs were not associated with any of the self-management behaviours, but were associated with psychosocial factors, with illness beliefs accounting for 52% and 32% of the variance in anxiety and positive well-being, respectively. The two illness beliefs that significantly contributed to the prediction of anxiety and positive well-being were consequences and personal control. Lower levels of perceived consequences and higher levels of perceived personal control were associated with lower levels of anxiety and higher levels of positive well-being.

A further two studies investigated illness perceptions in association with engagement with health services. One of the studies, which was conducted by Lawson et al. (2004), found that individuals with more negative views on consequences, control, and timeline did not seek regular-care (non-attenders),

compared with the group who sought regular-care (attenders). The study also showed that the individual's perceived control predicted clinic appointment attendance. The second study, which was conducted by Kibbey et al. (2013), used the BIPQ and a battery of psychosocial questionnaires to investigate barriers and enablers that contribute to engaging youth in diabetes services. The study found that unsatisfactory previous experiences with health providers were contributors to client disengagement from diabetes health services. In addition, non-attenders had significantly more threatening views of diabetes and emotional distress.

In summary, the above studies suggest that, in young people with type 1 diabetes, although illness perceptions did not seem to play a consistent direct role in regulating diabetes self-management behaviours or HbA1c, they do have an impact on the regulation of psychosocial aspects, which in turn may have an impact on diabetes management. The differing study designs, analyses, and combination of predictor and outcome variables between studies may have contributed to discrepancies in outcomes and interpretations. In addition, factors such as small sample size and homogeneity of the sample limit the generalisability of results. For these reasons, further investigations are still required to clarify the associations between diabetes control and illness perceptions.

### **Self-efficacy**

Self-efficacy has been defined as "people's judgments of their capabilities to organise and execute courses of action required to attain designated types of performances" (Bandura, 1986, p. 391). It, therefore, represents an individual's belief

in their ability to achieve tasks and to conquer challenges. Self-efficacy is a core construct in Bandura's social cognitive theory (Bandura, 1986, 1997, 2001), which describes four main components to developing self-efficacy: personal experiences of success or failure, observed experiences of others (e.g., providing a model in succeeding or failing in certain situations or actions), social pressure of encouragement or discouragement from another person, and personal perception of physiological factors being linked to one's ability or inability to accomplish tasks (e.g., attributing signs of distress in stressful situations to self-efficacy rather than normal bodily reactions to that situation).

Self-efficacy beliefs have an impact on many aspects of human functioning and can affect QoL and health outcomes (Kent, 2011). Behavioural choices can be affected by how confident a person feels in achieving particular goals and if he or she chooses to undertake or avoid particular tasks (Bandura, 2001; Strecher, McEvoy DeVellis, Becker, & Rosenstock, 1986). Self-efficacy beliefs can also affect motivation to engage in and complete tasks, to persevere when faced with challenges, and to maintain long-term stimulus (Bandura, 1997, 2001; Pajares, 1997).

Self-efficacy is of critical importance to the management of illnesses that involve complex routines and require long term maintenance (Bandura, 1997; Freij, Svarin, Steurer-Stey, & Puhan, 2009). In relation to the topic of this thesis, the above suggests that self-efficacy is a strong candidate for studies on diabetes control and self-management. This is because individuals with diabetes are involved in a demanding self-management regimen in which stronger self-efficacy is likely to facilitate diabetes self-management.

A number of studies have investigated self-efficacy in relation to clinical, behavioural, and psychosocial diabetes outcomes (Celano, Beale, Moore, Wexler, & Huffman, 2013; Krichbaum, Aarestad, & Buethe, 2003; Mohebi, Azadbakht, Feizi, Sharifirad, & Kargar, 2013). Generally, research has shown strong and consistent evidence of the influence of self-efficacy on diabetes management and outcome across different age groups with type 1 and type 2 diabetes (Celano et al., 2013; Krichbaum et al., 2003; Mohebi et al., 2013). Studies have explored the direct influence of self-efficacy on diabetes-related aspects and in mediational models, including glycaemic control and diabetes self-management behaviours. Stronger self-efficacy in both adult and adolescent samples has been found to predict good adherence to diabetes self-management behaviours (Hurley & Shea, 1992; McCaul, Glasgow, & Schafer, 1987; Padgett, Senecal, Nouwen, & White, 2000; Temple, 2003). Self-efficacy has been found to be a significant predictor of HbA1c, with greater self-efficacy associated with lower HbA1c (Aalto & Uutela, 1997; Griva et al., 2000; Rubin, Peyrot, & Saudek, 1993; Talbot, Nouwen, Gingras, Gosselin, & Audet, 1997). Research has also found self-management to mediate the association between self-efficacy and HbA1c (Griva et al., 2000; Hackworth et al., 2013; Johnston-Brooks, Lewis, & Garg, 2002); self-efficacy was a significant predictor of overall and specific self-management components and subsequently HbA1c (Austin, Guay, Senécal, Fernet, & Nouwen, 2013). In addition, self-efficacy mediated the relationship between self-management and several diabetes-related factors including diabetes distress and motivation to engage in dietary self-management (Knecht; Queralt, 2010; Sacco et al., 2007; Syrjala, Knecht, & Knuuttila, 1999). Stronger self-efficacy mediated mastery skills and adherence to diabetes self-management behaviours in young people with diabetes. Lower self-efficacy, on the other hand,

mediated the relationship between non-adherence to SMOBG and non-supportive parenting styles (Herge et al., 2012; Law et al., 2002; Ott, Greening, Palardy, Holderby, & DeBell, 2000). Finally, self-efficacy was significantly associated with diabetes-related QoL and social functioning – stronger self-efficacy was associated with better outcomes (Aalto, Uutela, & Aro, 1997).

Research findings have demonstrated the important role of self-efficacy in relation to clinical and behavioural aspects for individuals with type 1 diabetes (Hanna et al., 2013; van der Ven et al., 2003). The findings suggest that self-efficacy is of particular importance in adolescence and young adulthood, because it is a key factor for improved diabetes control and self-management behaviours (Hackworth et al., 2013). The next section details studies that recruited individuals with type 1 diabetes in the adolescent and young adulthood age range. It presents research that examined self-efficacy in association with HbA1c and adherence to diabetes self-management, using either a direct effect model, or mediational models, or both. Studies that included HbA1c in both direct and mediational effect relationships are discussed first, then research that investigated HbA1c in either direct associations or mediational associations. This is followed by studies that only used self-report measures and other diabetes control indices.

### **Youth with type 1 diabetes and self-efficacy**

Johnston-Brooks et al. (2002) conducted a cross-sectional and longitudinal study to explore the role of self-efficacy in predicting self-management and HbA1c, and to examine self-management as a mediator in the relationship between self-efficacy and HbA1c. Young adults ( $N = 110$ ) aged 18-35 years old with type 1

diabetes from Colorado, USA, participated in the research. This research used a panel study design with baseline measurement, follow-up at 3 and 6 months, and an extra follow-up for HbA1c data at 9 months. The baseline HbA1c sample mean was 8%. Predictor variables included self-efficacy and outcome variables included HbA1c and adherence to self-management behaviours (diet, exercise, SMOBG, medication use). The study used a self-efficacy measure that had been used in an earlier study (Kavanagh, Pierce, Lo, & Shelley, 1993).

Cross-sectional analyses revealed that greater self-efficacy was a significant predictor of better self-management ( $\beta = 0.63, p < 0.0005$ ), and it significantly predicted lower HbA1c ( $\beta = -0.30, p < 0.05$ ). In a different model, self-management was found to mediate the association between self-efficacy and HbA1c. Overall self-management and SMOBG were found to significantly mediate the HbA1c and self-efficacy relationship. In the longitudinal part of the study, predictors were regressed on the furthest points of outcome variables from baseline, and this provided stronger evidence for the stability and predictability of variables. The regression analysis in the longitudinal study of the direct effects demonstrated that greater self-efficacy longitudinally predicted better adherence to dietary and exercise self-management behaviours ( $\beta = 0.36, p < 0.005$ ;  $\beta = 0.29, p < 0.05$ , respectively) and also predicted lower HbA1c ( $\beta = -0.3, p < 0.005$ ). An examination of the mediational effects showed that higher levels of self-efficacy at baseline significantly predicted dietary self-management during follow-up. The findings also showed that HbA1c was reliably predicted at the 9 months follow-up by the mediated relationship of self-efficacy and diet self-management.

The study by Johnston-Brooks et al. (2002) contributed to gaps in knowledge

with regards to empirical evidence of direct and mediational relationships among the variables of self-efficacy, HbA1c, and diabetes self-management. Of note is that the study population included not only youth but also adults. It is recommended that future research either controls for the age factor or the research is conducted with a more specific age range (e.g., youth), because this would help to clarify associations of factors for this developmental stage.

In the study by Griva et al. (2000), which has already been discussed in the context of illness perception in this chapter, self-efficacy was also investigated in association to HbA1c and self-management. Self-efficacy was measured by the Generalised Self-efficacy scale and the Self-efficacy for Diabetes Scale (DSES). Bivariate correlations showed several significant associations amongst the study variables. Stronger diabetes-specific self-efficacy beliefs were associated with fewer diabetes-related symptoms ( $r = 0.29, p < 0.01$ ) and fewer perceived consequences ( $r = 0.39, p < 0.001$ ). Better metabolic control (i.e., lower HbA1c levels) was significantly correlated with a greater sense of both generalised and diabetes-specific self-efficacy ( $r = -0.37$  and  $r = 0.51$ , respectively,  $p < 0.01$ , and  $p < 0.001$ ). Adherence was significantly associated with diabetes self-efficacy ( $\beta = -0.424; p < 0.0005$ ) and perceived identity ( $\beta = -0.387; p < 0.001$ ). Furthermore, those who had poor adherence to SMOBG had lower generalised and diabetes-specific self-efficacy expectancies ( $t(62) = -4.25; t(62) = 5.02, p < 0.001$  respectively), compared to those who had good adherence to SMOBG. Similarly, those with poor adherence to exercise had lower generalised self-efficacy and control beliefs than those in the good adherence group ( $t(62) = 2.59, p < 0.01$  and  $t(62) = 2.82, p < 0.006$ , respectively).

A regression model that accounted for the variance in total adherence did not find self-efficacy to contribute significantly to a partial explanation of the variance in total adherence, and as mentioned previously, perceived control only contributed 39% of the variance. In a hierarchical multiple regression analysis that accounted for variance in HbA1c, diabetes-specific self-efficacy and generalised self-efficacy contributed to 29.9% ( $\beta = 0.548$ ;  $p < 0.00001$ ) and 4.4% ( $\beta = -0.24$ ;  $p < 0.01$ ) of the variance in HbA1c, respectively. The addition of adherence to the model accounted for another 15.8% of the variance in HbA1c, and adherence was a significant predictor of HbA1c. In addition, diabetes-specific self-efficacy was found to mediate the association between adherence and metabolic control.

Iannotti et al. (2006) investigated self-efficacy in association with glycaemic control and adherence. A new instrument, which is related to these factors, was constructed and validated as part of the study. This tool incorporated measures of self-efficacy for diabetes self-management (SEDM), and negative and positive outcome expectations for diabetes self-management (OEDM-N and OEDM-P, respectively). A total of 168 young people aged 10-16 years old with type 1 diabetes with a mean HbA1c of 8.3% ( $SD = 1.78\%$ ) from Maryland, USA, were recruited for this study. The adolescents were separated into two age groups: 10-12, and 13-16 year olds. Zero-order correlations showed that stronger self-efficacy in both age groups was significantly associated with better diabetes self-management ( $r = 0.25$ ,  $p < 0.05$ ;  $r = 0.37$ ,  $p < 0.001$ , in younger and older groups respectively). Furthermore, stronger self-efficacy and better adherence to diabetes self-management in the older age group were associated with lower HbA1c ( $r = -0.21$ ,  $p < 0.05$ ;  $r = -0.34$ ,  $p < 0.001$ , respectively). Stronger self-efficacy was positively correlated with fewer



negative perceived outcomes in both age groups ( $r = 0.48$  and  $r = 0.4$ , younger and older group respectively,  $p < 0.0001$ ).

These relationships were further investigated using hierarchical multiple regressions. The predictor variables included SEDM, OEDM-P and OEDM-N, and the outcome measures included reported adherence and HbA1c for the younger and older age groups. The younger age group regression model had a non-significant result, suggesting that self-efficacy did not predict adherence or HbA1c in that age group. The older age group model, however, revealed that self-efficacy was significantly associated with adherence and self-management. The contribution of self-efficacy in the variance of HbA1c was 5.5% ( $\beta = -0.26$ ,  $p < 0.05$ ) and 12.2% ( $\beta = 0.33$ ,  $p < 0.01$ ) for adherence. The regression analysis confirmed that stronger self-efficacy beliefs predicted better adherence to diabetes self-management and lower HbA1c levels. The results of this study suggest the important role of self-efficacy in older adolescents, who are expected to take more responsibility of their diabetes, compared to children.

A study by Young (2003) investigated the role of self-efficacy in predicting glycaemic control and adherence. The study recruited 50 adolescents (13-17 years old) with type 1 diabetes from the Auckland Diabetes Centre, New Zealand. The mean HbA1c at the start of the study was 8.6% ( $SD = 1.9\%$ ). Bivariate correlations revealed that self-efficacy, measured by the DSES, was associated with adherence ( $r = 0.31$ ,  $p < 0.05$ ). Greater self-efficacy was correlated with better adherence. Glycaemic control was associated with adherence ( $r = -0.38$ ,  $p < 0.01$ ), but not with self-efficacy. A higher level of adherence was correlated with lower HbA1c. Hierarchical regression analyses in this study included self-efficacy as a predictor of

two outcome measures: adherence and HbA1c. The models controlled for covariates, including age and gender. In a model that included the outcome variable HbA1c, age was a significant predictor of HbA1c. An increase in age was associated with a higher HbA1c ( $\beta = 0.33, p < 0.05$ ). Age in this model explained 10.2% of the variance of HbA1c. In this model, contrary to what was hypothesised, a stronger self-efficacy was associated with poorer HbA1c ( $\beta = 0.37, p < 0.05$ ). Self-efficacy contributed 8% of the variation in HbA1c. In a different regression analysis, including adherence as an outcome variable, self-efficacy did not significantly predict adherence.

Young (2003) presented evidence for the association between self-efficacy and HbA1c, such that greater self-efficacy predicted poorer HbA1c outcomes. The direction of this relationship, however, was different from that found in previous research where a significant association was reported between HbA1c and self-efficacy in UK youth (Griva et al., 2000). Given the conflicting results, there is a need for a further investigation of self-efficacy as a predictor of HbA1c in youth.

Another New Zealand study based in Auckland, which recruited adolescents (13-19 year olds) with type 1 and type 2 diabetes, examined self-efficacy in relation to diabetes self-management and HbA1c as part of a larger study (Singh, 2008). The mean HbA1c was 9%. The zero-order correlations presented significant associations between self-efficacy, self-management, and HbA1c. In a regression model, self-efficacy (measured by SEDM) was a significant predictor of self-management ( $\beta = 0.71; p < 0.01$ ). In a different model, HbA1c was not predicted by self-efficacy or by diabetes self-management. This study provided further evidence of the association between self-management and self-efficacy, but not for an association between self-

efficacy and HbA1c. This study had a mixed sample of both type 1 and type 2 diabetes, and the analysis represented an effect on the combined sample. Type 1 and type 2 diabetes are two distinctively different conditions despite the common factors between them (American Diabetes Association, 2014), and because of this separate analysis is required.

A descriptive study examined the correlations amongst HbA1c, self-efficacy, and emotional distress for a sample of 30 young adults (18-30 year olds) with type 1 diabetes (Burke, 2004). This was part of a larger study that assessed factors affecting diabetes self-management in college students. The participants were recruited from the University of Illinois at Urbana-Champaign, USA, and the sample was drawn from six separate university campuses. The study by Burke (2004) did not find any significant correlations between HbA1c and the self-efficacy scores. The study did, however, find that better emotional adjustment to diabetes was associated with stronger self-efficacy beliefs. This study only presented descriptive correlations and therefore conclusions that can be drawn are limited.

A study in Taiwan investigated the impact of self-efficacy beliefs on HbA1c in 52 Taiwanese adolescents (12-20 years old) with type 1 diabetes (Chih, Jan, Shu, & Lue, 2010). The mean HbA1c was 8.6% ( $SD = 1.6\%$ ). Pearson's correlation coefficient showed a significant association between self-efficacy and HbA1c ( $r = -0.3, p < 0.05$ ), suggesting that stronger self-efficacy was associated with better HbA1c. Logistic regression analysis, using HbA1 level  $< 7\%$  as a dependent variable, revealed that stronger self-efficacy was a significant predictor of HbA1c with an odds ratio of 1.63 (95% CI: 1.03, 2.59). To put this result another way, participants with stronger self-efficacy were 1.63 times more likely to achieve the

recommended HbA1c target. The study provides further evidence of the importance of self-efficacy in diabetes control, but because HbA1c was treated as a categorical variable this places a limit on the exploration of the association of HbA1c with other variables.

Hackworth et al. (2013) recruited 123 youth (13-25 years old) from urban and rural Victoria, Australia, to investigate the role of self-efficacy (measured by the DSES) in predicting self-management behaviours and HbA1c. The mean HbA1c was 8.3% ( $SD = 1.5\%$ ). This study investigated the direct and indirect relationship amongst the study variables. Pearson's correlations between variables included a significant relationship between self-efficacy and diabetes self-management ( $r = 0.32, p < 0.01$ ), but not with HbA1c. Although self-efficacy was not significantly correlated with HbA1c, it was hypothesised that self-efficacy had an influence on metabolic control through its effect on diabetes self-management, which was significantly associated with HbA1c. Structural equation modelling in this study showed that higher self-efficacy significantly predicted better diabetes self-management ( $\beta = 0.65, p < 0.01$ ), and subsequently higher levels of diabetes self-management predicted improved metabolic control ( $\beta = -0.31, p < 0.01$ ). This model found that self-efficacy contributed to metabolic control through its relationship path with diabetes self-management: Higher self-efficacy indirectly contributed to lower HbA1c.

In a mediational model, a pathway including self-efficacy linked to adherence, diabetes self-management, and HbA1c was examined in 70 young people (9-21 year olds) with type 1 diabetes from Hong Kong (Stewart et al., 2000). In the exploratory analysis section of this study, the bivariate relationships demonstrated

that self-efficacy, measured by the Littlefield (1992) self-efficacy scale, was significantly correlated with adherence but not with HbA1c. Stronger self-efficacy reflected better adherence to diabetes self-management. Regression analysis showed that self-efficacy had an influence on adherence, which in turn had an influence on HbA1c. This suggested that, similar to other research findings, stronger self-efficacy beliefs were associated with better adherence and subsequently lower HbA1c.

The stability of this model over time was further explored in an extended research of the same study. The later study examined longitudinal analysis of the above mentioned pathway by following up 56 participants 12-24 months post the initial participation (Stewart et al., 2003). Longitudinally, adherence was a significant predictor of diabetes control, but self-efficacy was not found to significantly predict adherence over time. The authors reported that this finding may be attributed to the weak reliability of the imported self-efficacy measure used (weak test re-test reliability). In addition, the broad age range and not controlling for the age factor as a moderator in this study may have influenced the longitudinal model outcomes.

A study conducted in Massachusetts, USA, examined whether self-efficacy in youth was related to metabolic control (Grossman, Brink, & Hauser, 1987). In this study the self-efficacy for diabetes scale (SED) was developed, validated and used. The sample consisted of 68 adolescents (12-16 years old) with type 1 diabetes. Metabolic control in this research was defined by four medical indices, which did not include HbA1c because it was not available for all participants during the study period. The four indices were: average blood glucose levels, urine glucose levels, urine acetones, and 24-hour glycosuria. The researchers determined a 3-point rating system for each of the four indices to represent level of control; these levels were

coded by an experienced paediatric/adolescent diabetologist. The sum of the four indices for each subject gave the total medical index.

A t-test found no difference in diabetes self-efficacy beliefs based on gender; consequently a combined sample analysis was used throughout the study. Scores of the total SED and the diabetes-specific component of SED were significantly associated with the total medical index ( $r = 0.25, p < 0.05$ ). Greater self-efficacy was associated with better metabolic control. The generic SED components were not found to be associated with metabolic control.

Results from this study are limited because of the scope of the analysis which only included basic statistical methods to describe associations between metabolic control and self-efficacy. Confirmatory statistical methods are required to test these associations (e.g., regression analysis). Furthermore, a more reliable outcome measure representing metabolic control (i.e., HbA1c) was not available for this study. Nonetheless, the results suggest that self-efficacy had an impact on blood glucose.

In a longitudinal study, self-efficacy was investigated in youth throughout the transitioning period from high school to post-high school and in association with diabetes self-management (Hanna et al., 2013). The study recruited 114 adolescents (aged 17-19 years old) with type 1 diabetes, with a mean HbA1c of 8.5% ( $SD = 1.4\%$ ), who were living with their parent or guardian, in Indianapolis, USA. Data were collected at two time points, the first time point (T1) was during the last 6 months of high school, and the second time point (T2) was collected in the year after graduation from high school. The study found an increase in diabetes self-

management progressing from high school to post-high school, and youth with higher levels of self-efficacy (measured by DSES) had better diabetes self-management. These findings were not associated with whether the youth was living with parents or not. Thus, this study provided evidence that self-efficacy is important for diabetes self-management regardless of the emergence period and the living situation.

The association of self-efficacy and adherence to diabetes self-management (diet, SMOBG, insulin injections, and exercise) was examined in youth with type 1 diabetes (Littlefield et al., 1992). This study recruited 193 youth (13-18 year olds) with type 1 diabetes in Canada. Descriptive analysis showed that self-efficacy was significantly correlated with adherence ( $r = 0.57, p < 0.001$ ), with higher self-efficacy associated with better adherence. In addition, adherence was negatively correlated with HbA1c ( $r = -0.24, p < 0.001$ ). HbA1c was only used to examine the validity of the adherence scale, and was not included in subsequent analysis. In the regression model the contribution of self-efficacy in predicting the variance in adherence was about 20% of the variance ( $p < 0.0001$ ).

This study used general self-report measures that were developed as part of the study; the reliability and validity of these measures were unknown, and this limits conclusions that can be drawn from the results. This study, however, suggested the importance of considering self-efficacy in interventions for youth with diabetes because it may have implications for diabetes self-management.

In addition to the above studies, which included multiple generic and specific components related to diabetes, there have been other studies which have

investigated self-efficacy in association with adherence to dietary self-management (Austin et al., 2013; Nouwen et al., 2009; Queral, 2010). Results from these studies followed a similar trend of significant associations in pathways, including self-efficacy and diabetes-related clinical, behavioural, and psychosocial factors. Findings from these studies suggested that self-efficacy has an influence on several diabetes domains, such that stronger self-efficacy is directly and indirectly correlated to positive diabetes outcomes.

In summary, self-efficacy has been investigated in diabetes research and has been found to be associated with diabetes control and self-management. Stronger self-efficacy beliefs have been consistently found to predict better diabetes management. Studies that have investigated the role of self-efficacy in predicting HbA1c have included children and adolescents, but rarely has this investigation been conducted in youth (15-24 year olds) with type 1 diabetes. Moreover, the studies that have, reported inconsistent results, and therefore further research is required.

### **Quality of Life (QoL)**

The concept of QoL has been extensively addressed in health research (Bakas et al., 2012). Quality of life comprises a broad range of aspects associated with daily functioning, which include physical, behavioural, and psychosocial well-being (Felce & Perry, 1995; Theofilou, 2013). In the context of diabetes research, investigating QoL assesses the impact of diabetes on emotional and psychosocial functioning and evaluates factors associated with diabetes control and self-management (Hornquist, Wikby, Stenstrom, Andersson, & Akerlind, 1995; Nieuwesteeg et al., 2012). Quality of life in different age groups with type 1 and type 2 diabetes has been found to be



associated with a broad range of diabetes outcomes including clinical, behavioural, and psychosocial (Hornquist et al., 1995; Imayama, Plotnikoff, Courneya, & Johnson, 2011; Naughton et al., 2014; Nieuwesteeg et al., 2012).

Studies of the QoL in individuals with diabetes have investigated generic health related QoL (HRQoL) and diabetes-specific QoL (de Wit, Delemarre-van de Waal, Pouwer, Gemke, & Snoek, 2007; Matza, Swensen, Flood, Secnik, & Leidy, 2004; Solans et al., 2008), and each have unique contributions towards understanding the QoL of individuals with diabetes (El Achhab, Nejjari, Chikri, & Lyoussi, 2007; Harding, 2001; Nansel et al., 2008). Generic HRQoL is useful when comparing individuals with diabetes with their healthy counterparts or with those who have other chronic conditions, and on a population level (Kiadaliri, Najafi, & Mirmalek-Sani, 2013; Solans et al., 2008). Although generic HRQoL is useful for some research objectives, diabetes-specific QoL can be utilised to learn more about specific populations, and to evaluate the effectiveness of interventions (Wiebe, Guyatt, Weaver, Matijevic, & Sidwell, 2003). Diabetes-specific QoL is a more focused multidimensional construct, which was found to be mostly associated with adherence and HbA1c, whereas the generic HRQoL is highly associated with depression (El Achhab et al., 2007; Nansel et al., 2008; Rubin & Peyrot, 1999). In this next section general key findings related to research on youth, and of relevance to this thesis, are summarised and the focus turns to studies that investigated QoL in youth with type 1 diabetes. This is followed by detailed review of literature investigating QoL in relation to diabetes control, as measured by HbA1c.

Youth with diabetes generally experience lower QoL compared to those without diabetes (Graue, Wentzel-Larsen, Hanestad, Båtsvik, & Søvik, 2003;

Kalyva, Malakonaki, Eiser, & Mamoulakis, 2011; Trento et al., 2013; Varni, Limbers, & Burwinkle, 2007). Nonetheless, findings from a few studies showed that youth with diabetes had similar HRQoL compared to those who do not have diabetes (Kristensen et al., 2014; Laffel et al., 2003; Lukács, Varga, Barótfi, Kiss-Tóth, & Barkai, 2012). Compared to youth with other chronic diseases, youth with diabetes had better HRQoL (Kalyva et al., 2011; Varni et al., 2007). Youth with better glycaemic control had better generic HRQoL compared to those with poor diabetes control (Graue et al., 2003; Kalyva et al., 2011; Wagner, Müller-Godeffroy, Sengbusch, Häger, & Thyen, 2005). Younger age was associated with better HRQoL, whereas older age was associated poorer QoL (Graue et al., 2003; Wagner et al., 2005).

The majority of the studies on diabetes-specific QoL reported that lower HbA1c was associated with better QoL (Abdul-Rasoul, Alotaibi, Abdulla, Rahme, & Alshawaf, 2013; de Wit et al., 2012; Guttmann-Bauman, Flaherty, Strugger, & McEvoy, 1998; Kalyva et al., 2011; Spitz & Kanani, 2006). This association, however, was not always detected (Graue et al., 2003; Grey, Boland, Yu, Sullivan-Bolyai, & Tamborlane, 1998; Ingersoll & Marrero, 1991; Kent, 2011; Vandagriff, Marrero, Ingersoll, & Fineberg, 1992), and one study, examining QoL reported that better glucose control was associated with higher worry and anxiety scores in Jamaican youth (Tulloch-Reid & Walker, 2009). In this study the anxiety and worry scale represented level of worries about money matters, concerns about the future and life stresses.

Other factors that have been found to be associated with QoL in youth with diabetes included age, gender, diabetes duration, and psychological attributes. Older

age was associated with poorer diabetes-related QoL (Abolfotouh, Kamal, El-Bourgy, & Mohamed, 2011; de Wit et al., 2012; Graue et al., 2003). Males had better QoL than females gender (Abolfotouh et al., 2011; Graue et al., 2003; Kent, 2011; Lukács et al., 2012; Trento et al., 2013). Poorer QoL was also associated with lower self-efficacy and self-esteem, depression, later age of onset, longer diabetes duration, fear of hypoglycaemia, and fear of complications (Abolfotouh et al., 2011; Kent, 2011).

### **Youth with type 1 diabetes and quality of life**

Various approaches and analytical methods have been used to explore QoL in relation to dimensions of type 1 diabetes, with a relatively large number of studies<sup>1</sup> examining this in young people (Abdul-Rasoul et al., 2013; Al-Akour, Khader, & Shatnawi, 2010; Al-Hayek et al., 2014; Anderson et al., 2014; Cutler, 2004; de Wit et al., 2012; Diem, Frost, Augustiny, & Radanov, 2004; Faro, 1999; Faulkner, 2003; Grey, 2012; Grey, Davidson, Boland, & Tamborlane, 2001; Guo et al., 2013; Hackworth et al., 2013; Hanna, Weaver, Slaven, Fortenberry, & DiMeglio, 2014; Hesketh, Wake, & Cameron, 2004; Hilliard et al., 2013; Hoey et al., 2001; Huang et al., 2004; Huggard, 2009; Kalyva et al., 2011; Kent, 2011; Kristensen et al., 2014; Laffel et al., 2014; Lawrence et al., 2012; Lukács et al., 2012; Malik & Koot, 2009; Nansel et al., 2008; Nardi et al., 2008; Naughton et al., 2014; Pereira et al., 2011; Puri et al., 2013; Reid et al., 2013; Skinner, Hoey, McGee, & Skovlund, 2006; Stahl-Pehe et al., 2014; Tan et al., 2005; Xiong et al., 2013).

Many of these studies presented descriptive analyses (e.g., bivariate

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<sup>1</sup> Intervention studies were excluded

correlations) as part of the preliminary investigations or as the main analysis component. The majority of the descriptive studies found significant zero-order associations between QoL and HbA1c – lower HbA1c was mostly associated with better QoL (Abdul-Rasoul et al., 2013; Cutler, 2004; de Wit et al., 2012; Faulkner, 2003; Guo et al., 2013; Huggard, 2009; Kristensen et al., 2014; Laffel et al., 2014; Nansel et al., 2008; Nardi et al., 2008; Puri et al., 2013; Xiong et al., 2013). One study, however, found that lower HbA1c was associated with worse QoL (Grey, 2012), and two other studies did not find any significant associations (Diem et al., 2004; Faro, 1999).

Confirmatory analysis methods (e.g., multivariate analysis) were also used, which provided stronger evidence for the examined relationships. The larger number of studies, which used inferential analysis, examined QoL as an outcome measure (Al-Akour et al., 2010; Al-Hayek et al., 2014; Grey et al., 2001; Hackworth et al., 2013; Hanna et al., 2014; Hilliard et al., 2013; Hoey et al., 2001; Huang et al., 2004; Kalyva et al., 2011; Kent, 2011; Lawrence et al., 2012; Lukács et al., 2012; Malik & Koot, 2009; Naughton et al., 2014; Stahl-Pehe et al., 2014). A fewer number ( $n = 6$ ) examined QoL as a predictor of diabetes outcome, such as HbA1c (Hesketh et al., 2004; Laffel et al., 2014; Reid et al., 2013; Skinner et al., 2006; Tan et al., 2005). Pereira et al. (2011) examined QoL as both a predictor and an outcome measure in its relationship with HbA1c. The two directions in investigating the relationship between QoL and HbA1c suggest that one can influence the other (i.e., a bidirectional relationship). The set of studies that analysed QoL as an outcome measure provided information on the impact of diabetes-related variables, such as HbA1c, on QoL. In contrast, the set of studies that had QoL as a predictor explored

the effect of QoL on diabetes outcomes, such as investigating the contribution of QoL in predicating HbA1c levels.

Research suggests that an individual's QoL can be predicted from diabetes control such that lower HbA1c partially predicts better QoL (Al-Akour et al., 2010; Al-Hayek et al., 2014; Hilliard et al., 2013; Hoey et al., 2001; Huang et al., 2004; Kalyva et al., 2011; Lawrence et al., 2012; Lukács et al., 2012; Malik & Koot, 2009; Naughton et al., 2014; Stahl-Pehe et al., 2014). This association, nevertheless, was not always detected, and specifically not always in the youth age sample (Hanna et al., 2014; Kent, 2011).

Another question remains open, which is whether an individual's QoL can influence and contribute to predicting diabetes control (as measured by HbA1c), and what the size of that influence is. This question has been rarely addressed for the population of youth (15-24 year olds) with type 1 diabetes. The present study examines QoL as one of several key predictors contributing to variations in HbA1c. The hypotheses and contributions of the present study are discussed later. The following presents a detailed review of research which included QoL as an independent factor in the prediction of HbA1c in youth with type 1 diabetes. Studies that included a continuous HbA1c variable are reviewed first, followed by studies that used a categorical HbA1c to conduct the statistical analysis.

A large scale study involving 2077 participants examined the relationship between QoL and HbA1c as part of a study validating a diabetes-specific QoL scale (Skinner et al., 2006). This study recruited adolescents aged 10-18 years with type 1 diabetes from 22 diabetes centres in 18 countries across Europe, Asia, and North

America. In this study, bivariate correlations indicated significant association between QoL and HbA1c. Regression analysis was used to explore the contribution of the QoL multidimensional construct in variations of HbA1c levels. A hierarchical regression model included the five diabetes-specific QoL subscales (four of which have multiple items): impact of diabetes, worries about diabetes, satisfaction with treatment, and satisfaction with life; and the fifth subscale that deals with a single item on health perception. The model also controlled for age and gender and found those factors to contribute 1.4% of the variance in HbA1c. The diabetes-specific QoL dimensions of symptom impact, future worries, and impact on activities contributed an additional 5.2% to the variance of HbA1c. Higher HbA1c was associated with poorer QoL.

This study demonstrated the role of QoL in predicting HbA1c, and had a strong statistical power because of the large sample size. The percentage of contribution of the QoL items in the regression model suggested that there remains a large unexplained proportion for the variation in HbA1c, which can be attributed to other factors. For this reason it would be useful to investigate other key factors that are known to have an effect on HbA1c and to test the strength of their relationship with QoL.

A more recent study conducted in Florida, USA, examined QoL as a predictor of HbA1c, and examined the QoL in a mediational relationship between adherence and HbA1c (Reid et al., 2013). The study recruited 70 children and adolescents (9-18 year olds) with type 1 diabetes from an outpatient paediatric endocrinology clinic. The mean HbA1c was 9.3% ( $SD = 2.1\%$ ). The Pediatric Quality of Life (PedsQL) Inventory<sup>TM</sup>–Core module and the PedsQL–Diabetes module were used to evaluate a

young person's QoL from the parent and young person perspectives. The parent report scores were significantly lower (representing lower QoL) than that of the young person report. The young person report scores had a significant correlation with adherence but did not have a significant correlation with HbA1c, unlike the parent report which had a significant relationship with both. For subsequent regression analysis, the authors used the parent report data because these results were similar to that found in previous research.

A multiple regression analysis was conducted to examine the relationships between QoL, diabetes control, and adherence (Reid et al., 2013). A full hierarchical model that controlled for several factors (e.g., demographic race and adherence) accounted for an adjusted- $R^2$  41.6% in predicting HbA1c; the QoL contribution was 14% of the variance in glycaemic control. The model suggested that higher QoL was associated with better glycaemic control ( $\beta = -0.425, p < 0.01$ ).

The second part of the QoL data analysis included inspecting the mediational relationship between adherence and glycaemic control. The findings provide evidence for the significant mediational role of QoL from the path of adherence to the outcome variable of HbA1c. Put differently, the significant relationship between adherence to diabetes self-management and better diabetes control can be partially explained by improved QoL. The study by Reid et al. (2013) presented further evidence that QoL is a significantly (directly and indirectly) associated with glycaemic control. This suggests the importance of QoL when addressing determinants contributing to poor diabetes control in young people. The study, however, included analysis of data of young participants through their parents' reports, rather than the young persons themselves. In addition, the age of the young

participants was not controlled for in the regression model and the sample included ages that belong to the diabetes groups of children and youth, which are quite distinct groups (Alberti & Zimmet, 2011).

The study by Pereira et al. (2011), which was discussed in the section on illness perception, presented evidence of the role of QoL in predicting HbA1c. The QoL in this study was assessed using a Portuguese version of the Diabetes Quality of Life Questionnaire (DQoL) (Pereira et al., 2011). This study found that poorer QoL predicted high values of HbA1c ( $\beta = 0.25$ ,  $p < 0.05$ ) and less adherence to diabetes control ( $\beta = -0.215$ ,  $p < 0.05$ ).

The TEENs study, which was a very large international study that included 20 countries and nearly 6,000 participants, investigated the association of QoL and HbA1c in a subsample ( $n = 1382$ ) that included youth with type 1 diabetes (Anderson et al., 2014; Laffel et al., 2014). The participant's age range in this subgroup was 19-25 year olds. The study included participants from 219 diabetes centres located in different countries: Europe, the USA, Latin America, the Middle East, Africa, and India. The average HbA1c in this sample was 8.4%. The QoL was assessed using PedsQL 3.0 Diabetes Module, which has five subdomains: diabetes symptoms, treatment barriers, treatment adherence, worries about complications, and communication. Logistic regression analysis was used to examine the association of each of the subdomains with HbA1c as a categorical variable. The categories are  $\text{HbA1c} < 7\%$  and  $\text{HbA1c} \geq 7\%$ . Participants who reported better QoL on the scales of diabetes symptoms, treatment barriers, and treatment adherence were more likely to meet the target HbA1c; with odds ratios, respectively: 2.16, 2.22, and 3.16.



The results of the above study suggest that QoL can predict the chances of meeting target blood glucose levels. Strengths of this study include the statistical power and that the age group was well defined to ages from the youth diabetes group. However, as stated earlier, including HbA1c as a categorical variable may limit full exploration of HbA1c associations with other variables. It is recommended that future research analyses HbA1c using a continuous variable to determine the contribution of QoL in the prediction of HbA1c.

The association between QoL and metabolic control was examined in Malaysian children and youth with type 1 diabetes (Tan et al., 2005). Quality of Life was measured by the DQoL. Participants ( $N = 52$ ) aged 12-20 years were recruited from an outpatient Paediatric Diabetes Clinic. The majority (78.8%) had an HbA1c of more than 8%; the mean HbA1c was 10.0% (median = 9.8%). Based on the HbA1c descriptive statistics, a cut-off HbA1c level was determined such that HbA1c  $> 10\%$  depicts poor control, and HbA1c  $\leq 10\%$  represents good control. By this definition for this sample, 22 participants had poor control and 30 had good control. Two parallel sets of analysis were conducted; each included a different cut-off point of HbA1c (i.e., 10% and 8%). Logistic regression was used to analyse the data with HbA1c as the dependent variable (*poor control* = 0, *good control* = 1) and QoL as an independent variable in the regression models.

The results showed that children and youth with better QoL were more likely to have better HbA1c control, based on the 10% cut-off. No significant associations between HbA1c category and QoL were detected in the data at the 8% cut-off point. Although this study presented some evidence for an association between HbA1c and QoL in analysing the 10% cut-off data, it is limited in statistical power, choice of

analysis, and HbA1c cut-off point for good glycaemic control. In normal circumstances HbA1c = 10% is classified in the poor glycaemic control group. Despite the results being similar to what has been found in previous research, the results might be misleading because a different cut-off point that defined the good glycaemic control group was used.

Changes in QoL in relation to metabolic control in 83 children and adolescents (5-18 year olds) were assessed over a period of two years (Hesketh et al., 2004). The participants were recruited from an outpatient clinic at the Royal Hospital in Melbourne, Australia. The baseline HbA1c mean was 8.1%. Two HbA1c categories (grouped participants) were created based on a cut-off point that lies in the 75th percentile, HbA1c 8.8.% – a statistically useful division. The QoL assessments were administered, using the Child Health Questionnaire (CHQ) with a parent proxy for 5-11 year olds, and CHQ adolescent self-report (12-18 year olds). This research monitored changes in the study variables from baseline to follow-up, and checked for the predictability of changes based on the baseline variables (i.e., HbA1c and QoL).

The baseline data for the parent report scores were stable from baseline to follow-up with no significant changes. In contrast to this, the adolescents' report scores had significant changes in many of the CHQ subscales. The mean HbA1c for the combined sample had significant changes from baseline to follow-up with a mean rise of 0.75% ( $SD = 1.1\%$ ), which suggested a deterioration in diabetes control. The study found that lower HbA1c levels at baseline predicted increases in HbA1c at follow-up, and this accounted for 25% of the variance in HbA1c change between baseline and follow-up. The children and adolescents QoL scores at baseline did not predict HbA1c at follow-up nor its change from baseline to follow-up, except for a

subscale that is related to physical functioning and well-being. The scores of this subscale predicted the follow-up HbA1c, and its change from baseline to follow-up.

This study provided an insight on the role of QoL in longitudinally predicting HbA1c, finding that physical functioning and well-being contributed to the predictability of HbA1c. In addition, findings from this study suggested that the children's QoL was more stable compared to that of adolescents. This finding, combined with the predictability of HbA1c from QoL, suggests the importance of assessing and targeting QoL for better diabetes control in adolescence, and potentially youth.

In summary, although there were numerous studies addressing the QoL construct in the context of diabetes research, there was a paucity of studies that investigate the role of QoL in predicting metabolic control. The general findings overwhelmingly indicated that better QoL is associated with better diabetes outcome. Nonetheless, most investigations addressed the effect of HbA1c on QoL, but not the opposite. Findings from the few studies of QoL as a predictor of HbA1c suggest that QoL plays a role in explaining variance of the HbA1c. The available research is still limited in its conclusions because of methodological weaknesses, such as weak statistical power, using the parent's rather than the adolescent's report, and analysing HbA1c as a categorical variable. Further investigations are required to explore and address gaps in literature with regards to QoL as a predictor of HbA1c. The following section discusses the significance of the present research, its aims, and the hypotheses of the present study.

## Significance, Aims, and Hypotheses

Illness perception, self-efficacy, and QoL are key psychosocial factors that have direct and indirect associations with critical behavioural and clinical diabetes outcomes, such as adherence and glycaemic control (Delamater et al., 2014). There are limited studies that investigate these factors both in the youth population and in relation to diabetes control. In New Zealand, the present study is the first to examine a combination of these psychosocial factors in relation to diabetes control in youth with type 1 diabetes. Between 2003 and 2011 four studies in New Zealand examined some of these factors in children and adults, and the samples age ranges included individuals from the youth group (Broadbent et al., 2011; Huggard, 2009; Singh, 2008; Young, 2003); no previous study has investigated any of these psychosocial factors with youth in Canterbury.

The study by Young (2003) presented evidence for a significant association between HbA1c and self-efficacy in adolescents aged 13-17 years old, but the direction of association contradicted previous research. The study by Huggard (2009), discussed earlier, presented only descriptive analysis and compared groups of *poor* and *good* diabetes control using the variables HbA1c, QoL, and illness representations. This study found significant associations between the study variables in the participants, whose age ranged from 11 to 17 years. The study by Broadbent et al. (2011), to investigate illness perceptions in association with HbA1c, had a wide age range that mostly represented an adult sample ( $M_{\text{age}} = 43.2$ ,  $SD = 20.57$ ). The fourth study, that by Singh (2008), had participants with both type 1 and type 2 diabetes in the sample and self-efficacy was not found to predict HbA1c. Thus far, the analyses have been descriptive, there have been a wide range of participant ages,

or samples have included participants with a mix of those with type 1 and type 2 diabetes, or the findings have been inconsistent with earlier research.

From the above it can be seen that there are no studies in New Zealand that examine a combination of the three psychosocial factors that are of interest for this thesis. In addition, of the studies that do examine one or two of the psychosocial factors, the age range does not include youth above 17 years of age and is therefore not representative of the entire diabetes youth population for whom research shows that diabetes self-management and control can be particularly problematic (Borus & Laffel, 2010; Hamilton & Daneman, 2002; Pinhas-Hamiel et al., 2014; Tan et al., 2005).

The current study also addresses some of the gaps in knowledge, at an international level, such as the combined and individual roles of QoL, self-efficacy, and illness perceptions in predicting glycaemic control. The examination of their contribution can inform diabetes care systems, and in particular interventions that target those with poor control.

The role of illness perception in influencing metabolic control is still unclear in youth with type 1 diabetes; at present, evidence is scarce and somewhat inconsistent. Only two quantitative studies have examined the association between illness perceptions and HbA1c in a sample of youth (Griva et al., 2000; McGrady, 2012). A further two studies investigated illness perceptions and HbA1c but there was a mix of children and adolescents, ranging in ages from 10-17 and 12-19 (Fortenberry et al., 2014; Pereira et al., 2011). Of the two, Pereira et al. (2011) did not control for the age factor. The latter two studies found that illness perceptions, in

children and adolescents, had direct associations with HbA1c and those relationships were in the expected directions (e.g., higher level of negative emotions predicted poorer HbA1c).

There was some degree of inconsistency in the findings of studies that had included adolescents and young adults (Griva et al., 2000; McGrady, 2012). The study by McGrady (2012) did not find significant associations (cross-sectionally or longitudinally) between illness perceptions and HbA1c. The study, however, did find significant mediational relationships that included: HbA1c, illness perception, self-reported adherence, and blood glucose monitoring frequency. These results suggest that illness perceptions have an indirect effect on HbA1c through other process variables. The study by Griva et al. (2000), in contrast, found illness perceptions had a direct relationship with HbA1c and their study showed that perceived consequences and identity explained 12.2% of the variance in HbA1c.

As a consequence, further research is required to explore and understand the direct and indirect associations between HbA1c and illness perceptions. It should be noted that the study by Griva et al. (2000) only presented evidence for the cognitive representations and did not include analysis of an emotional representation component. Emotional representations in association with HbA1c are still unexplored for the youth age range. The studies by Fortenberry et al. (2014) and Pereira et al. (2011) both found that higher negative emotions predicted poorer HbA1c in children and adolescents. There is, therefore, insufficient known about the contribution of different illness representations to HbA1c specifically for youth with type 1 diabetes.

The self-efficacy construct in young people with type 1 diabetes has been

evaluated previously in association with clinical, behavioural, and psychosocial diabetes outcomes. There are, however, very few studies that examine the direct influence of self-efficacy on HbA1c particularly for youth (see literature review section on self-efficacy). Of the studies discussed, only three investigated the role of self-efficacy in predicting HbA1c (Griva et al., 2000; Iannotti et al., 2006; Johnston-Brooks et al., 2002). One of the studies addressed it for the late childhood and early adolescence stages: 10-16 years old (Iannotti et al., 2006), and the other study included adults aged 25 to 35 years old in the research sample (Johnston-Brooks et al., 2002). For the youth diabetes group, Griva et al. (2000) provided evidence for the significant association of self-efficacy and HbA1c in a direct effect model. Self-efficacy alone predicted nearly 30% of the variance in HbA1c, which suggests this construct has an essential role in diabetes control. The sample from this study was homogenous and therefore further investigations with different samples are needed to clarify the direct association of self-efficacy in its relationship with HbA1c. It is also particularly important to conduct further research in this area. This is because findings from the aforementioned New Zealand study by Young (2003) showed a different direction for the relationship between HbA1c and self-efficacy, which contradicted that found in the above study by Griva et al. (2000).

No previous study has been conducted in Canterbury to examine the role of self-efficacy in predicting HbA1c specifically in youth with type 1 diabetes, and only two studies throughout New Zealand reported examining this construct in samples of adolescents that included 13-19 year olds with type 1 or type 2 diabetes (Singh, 2008), and 13-17 years old with type 1 diabetes (Young, 2003). The former study did not find a significant association of self-efficacy as predictor of HbA1c, while the

latter study (as mentioned above) found results that contradicted previous research.

Finally, although there have been many studies on QoL as an outcome measure in its relationship with HbA1c, there is little research on the role of QoL in predicting glycaemic control. Only two studies investigated this association in a sample of children and adolescents with type 1 diabetes (Pereira et al., 2011; Skinner et al., 2006). The first study had participants aged 10-18 years old, which found QoL (future worries and impact) to contribute 5.2% of the prediction of HbA1c; higher HbA1c was associated with poorer QoL (Skinner et al., 2006). The second study by Pereira et al. (2011) found that poorer QoL predicted high values of HbA1c ( $\beta = 0.25, p < 0.05$ ). The remainder of studies had limitations such as assessing QoL from the parents' reports rather than the adolescents' report; analysing HbA1c as a categorical variable; and setting a cut-off of 10% to differentiate good or poor diabetes control groups, which is well above recommended guidelines. These limit the conclusions that can be drawn from earlier research about the relationship of QoL as a predictor of HbA1c in youth aged 15-24 years old with type 1 diabetes.

The present study aims to contribute to the international and national body of knowledge. The specific aims of the present study include:

- a) describe key psychosocial characteristics of youth (15-24 years old) with type 1 diabetes in the CDHB catchment area
- b) explore descriptive inter-relationships amongst variables in this study, and in relation to HbA1c
- c) use confirmatory analysis in the form of multiple regression models, to investigate the relationship between these psychosocial characteristics and



glycaemic control

- d) determine the combined and individual contribution and effect size of illness perception, self-efficacy, and QoL in predicting HbA1c

In the present study it was hypothesised that youth with type 1 diabetes residing in Canterbury would follow a similar trend to youth in other countries in terms of their descriptive psychosocial characteristics and HbA1c. It was also hypothesised the direction of the relationships of the key psychosocial characteristics and HbA1c would follow trends found in similar studies: threatening views of diabetes would be associated with higher HbA1c levels, and weaker self-efficacy beliefs and poorer QoL would be associated with higher HbA1c. Furthermore it was hypothesised that diabetes control would be predicted by the combined psychosocial constructs, with a significant contribution from the individual factors.

## **Method**

### **Participants**

Letters of invitation to participate in the current study were sent to 248 youth (15-24 years old) with type 1 diabetes in the CDHB catchment area. The youth were identified from CDHB records as part of the study presented in Chapter 2 (Obaid et al., 2012a, 2012c). Descriptive information and demographic characteristics from the study in Chapter 2 (gathered before the Canterbury earthquakes) were used in the current study. Of the 248 youth contacted regarding participation in the current study, 56 agreed to participate (females = 33; males = 23), completed the questionnaires, and had a record of a recent HbA1c. This gives a response rate of 23%.

## **Measures**

Glycated haemoglobin (i.e., HbA1c) was used as the primary outcome measure and as an indicator of the level of diabetes control. This biomarker (see Chapter 1) is considered the gold-standard to monitor the progress of the diabetes condition, and the risk for developing diabetes-related complications (Bruns, 2007; Hanas et al., 2014). In the current study the most recent HbA1c records, taken within 6 months of completion of the questionnaires, were obtained from CDHB clinical records. The HbA1c data and demographic variables (e.g., age and gender) were collected according to the procedure outlined in Chapter 2.

The predictor variables in the current study represented three key psychosocial factors (i.e., illness representations, self-efficacy, and QoL), which are multidimensional constructs. The following measures were administered to the participants. The measures were selected based on their reliability, suitability for youth, and length of time they took to complete. One consideration was that the CDHB Diabetes Centre (associate host institution) wanted to minimise the time required to fill out the questionnaires. The questionnaires, Appendix 3.1, were sent post the Canterbury earthquakes. The following describes the measures used in the current study, including their psychometric properties.

### **The Brief Illness Perception Questionnaire (BIPQ)**

The original BIPQ, which was developed in New Zealand, was adapted from the longer 80-item Illness Perception Questionnaire-Revised (IPQ-R) (Broadbent et al., 2006; Moss-Morris et al., 2002). The BIPQ has nine items; each assessing an illness perception dimension (Broadbent et al., 2006). The BIPQ is a general measure

that can be applied to different illnesses; for example, it is acceptable to change the wording slightly to replace *illness* with *diabetes* (Broadbent et al., 2006).

The first eight BIPQ items are quantitative, whereas the ninth item is a qualitative open-ended question on the cause of illness. The BIPQ eight quantitative items are: consequences, timeline, personal control, treatment control, identity, coherence, concern, and emotions. The latter two items reflect emotional representations. Each dimension has a 10-point Likert scale; for example, the scores range from *no effect at all* to *severely affects my life*. The quantitative BIPQ items were used in this study, and the ninth item was excluded from the questionnaire<sup>2</sup>.

Stronger beliefs on identity, consequences, timeline, and emotional representations denote negative perceptions (Broadbent et al., 2006; Hagger & Orbell, 2003). The negative perceptions indicate a highly perceived symptomatic condition, more serious consequences and impact on life, and greater emotional reactions to an illness. In contrast, unless reversed, higher scores on the controllability and coherence depict positive perceptions, which reflect stronger beliefs on the manageability of the illness and recovery from it, and more understanding views of the illness (Broadbent et al., 2006; Hagger & Orbell, 2003).

A total BIPQ score (BIPQ-Total) can be also computed. Personal control, treatment control, and coherence scores are reversed and then added to scores of the remaining items. The overall score represents the degree to which the illness is perceived as threatening or benign. A higher score indicates a more threatening and

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<sup>2</sup> Permission was sought and granted from the authors to exclude the ninth item. The CDHB Diabetes Centre requested only including the quantitative items. In addition, the term illness was replaced with diabetes.

negative views about the illness (Broadbent et al., 2006). Research suggests stronger beliefs about diabetes as a threatening condition negatively impacts on diabetes control (Harvey & Lawson, 2009).

The BIPQ has the advantage of being a reliable quick measure that is easy to understand. This is useful in situations when time is limited; for example, when several other questionnaires are administered (Broadbent, 2010). Research on the psychometric properties of the BIPQ suggests it has good test-retest reliability, concurrent, and discriminant validity (Broadbent et al., 2006; Ng, 2012). Furthermore, findings from a translated version (into Farsi) that had a sample of young individuals with type 1 diabetes, showed cross-cultural validity, good reliability, and concurrent validity (Bazzazian & Besharat, 2010).

The psychometric properties in the original version were based on data from a general sample across multiple illnesses including a sample of 119 adults with type 2 diabetes (Broadbent et al., 2006). The study found the BIPQ scale had good discriminant validity in distinguishing between illnesses, such as diabetes, asthma, myocardial infarction and minor illnesses. That is, the scale has the ability to uniquely assess an illness identified by the distinct patient beliefs of that illness.

Broadbent et al. (2006) evaluated the test-retest reliability of the BIPQ using a sample of participants who had renal disease, retested three and six weeks from baseline. The Pearson's correlations were significant for all 8 items, with correlations of  $r = 0.42$  to  $r = 0.75$  (for the individual subscales) suggesting good reliability of the BIPQ, and the study showed good concurrent validity. The authors found that higher personal control was associated with lower HbA1c ( $r = -0.3$ ,  $p < 0.01$ ); higher

identity and treatment control beliefs were associated with poorer HbA1c ( $r = 0.25$  and  $r = 0.25, p < 0.05$ , respectively).

Bazzazian and Besharat (2010) recruited 300 individuals aged 18-30 years old with type 1 diabetes, to evaluate the psychometric properties of a translated Farsi BIPQ. The Pearson's correlations coefficients of the individual items (retested over four weeks) ranged from  $r = 0.5$  to  $r = 0.75$ , which suggests good reliability. The study also provided evidence for the applicability of the scale and its cross-cultural validity, with factor analysis showing that the BIPQ in this study was structurally equivalent to the original version. Furthermore, there were significant associations between HbA1c and majority of the BIPQ dimensions: consequence ( $r = 0.595, p < 0.01$ ), personal control ( $r = -0.638, p < 0.01$ ), identity ( $r = 0.760, p < 0.01$ ), concern ( $r = 0.129, p < 0.05$ ), coherence ( $r = -0.177, p < 0.01$ ), emotional response ( $r = 0.549, p < 0.01$ ), and this also provides evidence of the concurrent validity of the BIPQ.

### **Self-Confidence in Diabetes Self-care (CIDS)**

The Self-Confidence in Diabetes Self-care (CIDS) assesses diabetes-specific self-efficacy in individuals with type 1 diabetes (van der Ven et al., 2005). More specifically, the CIDS assesses the perceived ability to perform self-management tasks specifically constructed for individuals with type 1 diabetes. The CIDS has 21 items which are rated on a 5-point Likert scale (van der Ven et al., 2003). This scale ranges from 1 (*No, I am sure I cannot*) to 5 (*Yes, I am sure I can*). Each CIDS item begins with, "I believe I can . . .". For instance: "I believe I can check my blood glucose at least two times a day". A total score is calculated by the summation of the

CIDS items, and then these are transformed to a 0-100 scale with higher scores indicating greater self-efficacy (van der Ven et al., 2005). Greater self-confidence in carrying out diabetes self-management tasks has been mostly found to positively influence diabetes control (Littlefield et al., 1992; Ott et al., 2000; van der Ven et al., 2005).

The CIDS has the advantage of being specific to type 1 diabetes and evaluates diabetes-specific self-efficacy rather than generic self-efficacy, a factor that is consistent with recommendations in the literature review section above. Furthermore, CIDS is easy to understand, and takes only a few minutes to fill out (van der Ven et al., 2003). The CIDS is a valid and reliable measure based on its psychometric properties as reported in the original research by van der Ven et al. (2003). The original research involved USA ( $n = 190$ ) and Dutch ( $n = 151$ ) participants ( $>18$  years old) and the scale was constructed using two languages concurrently: English and Dutch.

The original research presented evidence for the excellent internal consistency and test-retest reliability of the CIDS scale in both samples (van der Ven et al., 2005). The Cronbach alpha was more than 0.8, and the test-retest Spearman's coefficient was 0.85 ( $p < 0.0001$ ) (van der Ven et al., 2003). In addition, the CIDS had good concurrent validity. Two of the outcome measures used in evaluating the scale's concurrent validity were glycaemic control, as measured by HbA1c, and diabetes self-management behaviours scale. The English version CIDS scores were significantly associated with HbA1c ( $r = -0.25$ ,  $p < 0.005$ ), but the Dutch version scores were not. The self-management behaviours were significantly associated with CIDS in both samples (USA,  $r = 0.42$ ; Dutch,  $r = 0.44$ ;  $p < 0.0001$ ). These

correlations suggest that greater self-efficacy is associated with lower HbA1c levels, and with higher level of adherence to self-management behaviours. The high psychometric similarities between the two concurrent scales (i.e., English and Dutch versions) indicated the cross-cultural validity.

### **Pediatric Quality of Life Inventory™ Diabetes Module (PedsQL 3.2)**

The Pediatric Quality of Life Inventory™ Diabetes Module (PedsQL 3.2) assesses diabetes-specific QoL (Varni et al., 2003; Varni et al., 2012). It has 33 items which are categorised in five dimensions. These are: diabetes symptoms (*About my diabetes*), treatment barriers (*Treatment I*), treatment adherence (*Treatment II*), worries about complications (*Worry*), and communication related to diabetes (*Communication*). The items are scored on a 5-point Likert scale. The scores are reversed and then transformed to a 0-100 scale. Higher scores indicate lower problems with that particular aspect (Varni et al., 2003). For example, a higher score on the treatment adherence scale indicates not having problems with adhering to the diabetes self-management tasks. Better treatment adherence positively affects diabetes control (Nansel et al., 2008; Varni et al., 2003). A total score of the PedsQL scale (PedsQL-Total) can be computed by summing scores of the 33 items (i.e., dimensionless items). A higher score indicates fewer problems associated with overall diabetes-specific QoL.

The PedsQL 3.2 takes about five minutes complete and is suitable to use for youth with type 1 diabetes (Varni et al., 2003; Varni et al., 2012). The PedsQL 3.2 module has two slightly different versions: Teen (13-18 year old) and Adult (>18 year old) reports. The difference between the two versions is minimal and mainly in

the questionnaire wording to make it age appropriate. For example, in the Teen's report: "My parents and I argue about my diabetes care", in the Adult's report: "My spouse, significant other, and/or other family members and I argue about my diabetes care".

The PedsQL 3.2 was derived from a previous version, PedsQL 3.0 diabetes module. The latter measure was revised so that it is more suitable for all patients with type 1 diabetes, including newly diagnosed patients. The creators of the measures recommended using the modified version instead of the older version for all individuals with type 1 diabetes (Varni et al., 2012). The process of deriving PedsQL 3.2 involved conducting in-depth interviews with individuals with type 1 diabetes and a qualitative analysis of the interviews was carried out to create the modified version. There is no published research reporting on the psychometric properties of the PedsQL 3.2; rather, there is an assumption that the evidence for the reliability and validity of the PedsQL 3.0 also applies to the PedsQL 3.2.

Research on the psychometric properties of the PedsQL 3.0 suggest it has good internal consistency, with a Cronbach alpha of 0.8 for the total score (Nansel et al., 2008; Varni et al., 2003). In addition, the reliability coefficients of the five dimensions are also at an acceptable level. The treatment barriers, treatment adherence, and worry had a Cronbach alpha between 0.6 and 0.7, and the remaining two items (i.e., diabetes symptoms and communication) had an alpha of more than 0.7 (Varni et al., 2003). The PedsQL 3.0 was significantly associated with several outcomes measures (e.g., HbA1c and adherence). Findings from analysing data of one of the two cohorts in this study showed that HbA1c was significantly associated with the total score ( $r = -0.26, p < 0.01$ ), diabetes symptoms ( $r = -0.24, p < 0.05$ ),



treatment barriers ( $r = -0.23$ ,  $p < 0.05$ ), and treatment adherence ( $r = -0.23$ ,  $p < 0.05$ ). These results suggest that lower HbA1c levels were associated with fewer problems of diabetes-related QoL.

### **Statistical Analysis**

Descriptive and inferential statistical analyses were carried out to investigate the psychosocial characteristics of adolescents and young adults with type 1 diabetes in association with glycaemic control. Prior to conducting the analyses, the reliability of the questionnaires was checked. The psychosocial data were then investigated for patterns and descriptive correlations, before conducting the confirmatory analysis. The preliminary analyses guided the investigations of the role of the psychosocial factors in predicting glycaemic control (HbA1c).

The psychosocial factors dataset was missing eight data points. Incomplete data ( $n = 8$ ) were imputed by computing a truncated mean of the scores (see William, 2011). The following is an example of how this was computed: if an answer was missing from the CIDS scale (21-items), the truncated mean was based on 20 observations instead of 21. The method requires at least 50% of the scores to be recoded. This was easily achieved because very few observations were missing from the dataset. Data from the questionnaires were processed and analysed using Statistical Package for the Social Sciences (SPSS 19) and R-Gui (Braun & Maindonald, 2010; Kinnear & Gray, 2012; R Core Team, 2014).

The reliability of the measures used in the current study was assessed through evaluating their internal consistency, using the Cronbach alpha (Bland & Altman, 1997; Cronbach, 1951; Gliem & Gliem, 2003). This reliability index is suitable to

use for measures with multiple items administered to participants in a cross-sectional design, such as that in the current study (Bland & Altman, 1997; Gliem & Gliem, 2003). Cronbach alpha above 0.7 indicates acceptable internal consistency and higher values reflect more reliable measures with stronger internal consistency (Bland & Altman, 1997; Gliem & Gliem, 2003). Conversely, a Cronbach alpha that is below 0.7 needs to be interpreted with caution, because lower values suggest weaker internal consistency (Gliem & Gliem, 2003).

The descriptive analyses included exploring the bivariate correlations between the study variables. The analyses involved the continuous variables: HbA1c, age, and questionnaire scores. The bivariate interrelationships in the current study were evaluated using the Pearson Product Moment Correlation (PPMC), also referred to as Pearson's correlation (Lomax & Hahs-Vaughn, 2012). The PPMC coefficient ( $r$ ) was used to indicate how linearly dependent the variables are. The  $r$  range is between -1 and 1. A perfect linear relationship between two variables has an absolute  $r$  value of 1 (i.e.,  $|r| = 1$ ); whereas zero indicates no linear relationship. The sign of  $r$  determines the direction of the relationship. The strength of the correlation is determined by the  $|r|$  value which can be classified as: small correlation ( $0.1 \leq |r| < 0.3$ ); medium correlation ( $0.3 \leq |r| < 0.5$ ); and large correlation ( $0.5 \leq |r| \leq 1.0$ ) (Cohen, 1988; Cohen, 1992). It should be noted that the relationship between the study variables (e.g., HbA1c) and the gender variable was also explored. The categorical variable of gender was analysed using independent-samples t-tests to compare differences between females and males in relation to the study variables.

The association between the psychosocial characteristics and HbA1c was investigated using regression analysis. Regression analysis was used to investigate

the relationship between HbA1c (outcome variable) and the questionnaire scores (predictor or explanatory variables). Age and gender were controlled for. Since there were more than two predictors involved in the regression analysis, multiple linear regression (MLR) was utilised (Chatterjee & Simonoff, 2013; Cohen, Cohen, West, & Aiken, 2003; Kahane, 2008; Schuster & Eye, 1998; Su & Yan, 2009). Conditions to use MLR analysis were checked and assumptions were validated (Chatterjee & Simonoff, 2013). Guidelines of the MLR analysis and validation included inspecting the level of measurement, appropriate sample size, scatter plots, bivariate relationships of HbA1c and the questionnaire scores, potential outliers, multicollinearity, and residuals plots of the fitted models (Cohen et al., 2003; Simon, 2003). The residuals diagnostic plots included inspecting various scatter plots to check linearity of the model, homogeneity of the residuals, and to check leverage and Cook's distance of the residuals (Fox, 1991; Stevens, 2012). The residuals were also inspected for normality with the aid of the quantile-to-quantile (QQ) plots (Snijders & Bosker, 2011). Reliable and parsimonious models were derived. The MLR procedures and guidelines are outlined below.

The variables level of measurement and sample size in this study were first checked for adequacy for an MLR model. There need to be at least two predictor variables (metric or dichotomous) and one outcome variable (metric) to be able to apply an MLR model. The ratio of cases per predictor was calculated to ensure that the sample size was suitable to provide reliable correlation estimates. The guidelines specify that a ratio of minimum five cases per predictor (5:1) is required to produce a reliable model (Green, 1991; Osborne & Costello, 2004).

The bivariate relationships table was then used to aid in making informative

selections of variables to build meaningful regression models. The Pearson's correlation coefficient is a descriptive measure of the bivariate relationships and its strength, which can guide variables selection for regression analysis. It should be noted, however, in a regression model the relationship of an explanatory variable with an outcome variable can be described while taking away the effect of another variable or several other variables (Cohen et al., 2003). This means that the correlation coefficients and statistical significance of the effect of individual variables may change depending on which combination of variables are included in or omitted from the model (Cohen et al., 2003).

In the current study, a decision was made to include a comprehensive representation of all the variables that have been previously found to have an association with HbA1c. This meant that this analysis also included variables that did not present a significant association with HbA1c in the current study. The selection of certain variables (e.g., total score or separate dimensions) was guided by results from the interrelationships and extent of linear dependency among variables (using the bivariate correlations table). The selection of variables also complied with the acceptable level of cases to variables ratio in a regression model.

The scatter plots of the variables in association with HbA1c were also examined to identify possible influential points. Data points of HbA1c equal to or greater than 138 mmol/mol differed from other groups of observations in all plots. These were suspected as influential observations. It was statistically determined whether these points (or any other observations) were outliers after implementing MLR models.

There are several methods to statistically identify outliers and influential points. These include checking the leverage, Cook's distance, DFFITS (standardised difference in fit statistic), and DFBETAS (scaled difference in Beta). These statistics are used to test how influential each point is in a regression procedure – an R-command (*influence.measures*) can be used to check these (Boomsma, 2014; Chatterjee & Simonoff, 2013; Simon, 2003; Yan, 2009). The leverage statistics identify observations that are far away from corresponding average predictor values and the potential influence of these observations on a fitted regression model. Guidelines of this indicate that a leverage value needs to be less than the value of twice the number of predictors divided by the number of cases (i.e.,  $2p/n$ ) (Boomsma, 2014; Stevens, 2012). Cook's distance is a measure of changes in regression coefficients when an observation is deleted – it identifies problematic points, affecting a regression model, and a value less than 1 is an acceptable Cook's distance (Boomsma, 2014; Stevens, 2012). The DFFITS is a scaled measure of the change in the predicted value for the  $i^{\text{th}}$  observation and is calculated by deleting the  $i^{\text{th}}$  observation. The DFFITS is similar to Cook's distance, a large value indicates that the observation is an outlier in the  $x$  domain, DFFITS need to be less than 1 (Boomsma, 2014; Stevens, 2012). The DFBETA measures the scaled change in each estimated *beta* coefficient when the  $i^{\text{th}}$  observation is deleted from the regression, a value of less than 1 is acceptable (Boomsma, 2014; Stevens, 2012).

After identifying potential outliers, these were closely examined to check for any errors and if they belonged to a particular group of observations. The model was then run, with and without the outliers, to investigate the effect of removing these points on a regression model. Checking the stability of the model included testing for

changes in effect sizes, significance levels ( $p$ -value), and coefficients sign. If there were considerable changes in any of these, the outliers should be removed from the dataset. This is because of their influence on the model and its reliability.

In addition to identifying outliers, the model fit was examined. To examine this, the standardised and studentised residuals of each point were checked for goodness of fit of the regression line (Boomsma, 2014; Chatterjee & Simonoff, 2013). Studentised residuals are the standardised residuals with the  $i^{\text{th}}$  case removed from the equation; where the standardised residuals are the raw residuals (i.e., the difference between the data response and the fitted response) divided by the standard deviation of the residuals (Boomsma, 2014; Stevens, 2012). Theoretically, points having standardised/studentised residuals between  $-2.5$  and  $2.5$  are with a usual response compared with the predicted value from the model (Chatterjee & Simonoff, 2013). Points outside this range are potentially outliers and could influence the model specifications (Chatterjee & Simonoff, 2013).

The software R-Gui can produce plots which automatically detect and flag influential points (Boomsma, 2014; R Core Team, 2014). These plots include a graph of standardised residuals versus leverage. This plot identifies outliers with high leverage and high residuals. Furthermore, points with unacceptable Cook's distance range are marked on this plot. Points with standardised residuals outside the guidelines are also identified on a normality Q-Q plot of residuals. Further to using the diagnostic plots to capture potential outliers, the plots can be used to validate other MLR assumptions. These include testing for the normality of the residuals (the theoretical and the observed quantiles need to coincide), model misspecification (the residuals need to be independent of the fitted values), and homogeneity (constant

variance of the residuals). Violations to the MLR assumptions may cause biased coefficients and invalid t-statistics, and the validity of the  $p$ -values of the regression coefficients can be affected (Kitagawa, 2010).

Multicollinearity was also examined. Multicollinearity exists when two or more model predictors are highly linearly dependent (strongly correlated with each other), which could lead to identification problems (Cohen et al., 2003; Hutcheson & Sofroniou, 1999). The presence of multicollinearity within a set of predictors can cause misinterpretation of the significance of individual independent variables in the regression model. Predictors used in building a model should be relatively independent of each other. An examination of the bivariate relationships could reveal potential collinearity amongst variables, if the absolute value of Pearson's correlation coefficient is greater than 0.8 (Argyrous, 2011; Chen & Popovich, 2002; Hutcheson & Sofroniou, 1999). A more formal measure for multicollinearity is the Variance Inflation Factor (VIF), which is a measure of the amount of multicollinearity in a set of multiple regression variables. The VIF value should be less than 10 in regression models (Hutcheson & Sofroniou, 1999; Mason & Perreault, 1991; O'brien, 2007). Tolerance is also a measure of collinearity; its guideline is that a tolerance value less than 0.1 indicates that a variable is linearly dependent on other variables, and the variable under consideration should be investigated further (Hutcheson & Sofroniou, 1999; O'brien, 2007).

Assumptions validations and guidelines are important in deriving scientifically adequate regression models. A reliable and good explanatory model could be selected based on different criteria. Different models can be built given a set of predictors. Selecting variables to build a model can be based on including all

potential predictors in the model or combinations of variables, assuming that either method is possible from a practical perspective. In the current study there were 18 independent variables (including the questionnaires subscales), with hundreds of possibilities of equations to include combinations of variables. Given that this was not feasible, the MLR assumptions need to be validated for all models while in the process of selecting an optimal model. Alternatively, simultaneous forced entry (SPSS: *Enter*) of a set of selected variables can be used to fit a model; the selection can be based on previous research findings and strength of bivariate relationships in the current study. In addition, systematic methods could be used to eliminate or add variables, to yield a good quality and parsimonious model. Systematic methods include Backward selection and Forward selection methods (Stevens, 2012).

The Backward elimination procedure starts with a maximum model and then starts eliminating variables according to the  $p$ -value (alternatively the effect size can be used), the highest  $p$ -value gets removed first, and stops when it reaches a pre-specified threshold (e.g.,  $p$ -value  $< 0.1$ ). In contrast, the Forward selection method starts with no variables in the equations (intercept-only model), and then variables are introduced one by one. Variables with stronger effect sizes (in either direction) are kept in the model, weaker effect sizes are eliminated as they are entered and in relation to other variables in the equation. The Backward and Forward selection methods could produce several models that are potentially valid, choosing an explanatory model could be filtered further by using other criteria.

The coefficient of multiple determination ( $R^2$ ) can be used to determine the quality of a model (Linneman, 2011). This has a range from 0 to 1, where 1 is a perfect fit of the model to the sample observations. The  $R^2$  is described as the



proportion of variance explained by regression, or a summary of the explanatory power of the regression (Linneman, 2011). However, adding more variables to a model always increases the value of this, which may be misleading when comparing models having a different number of explanatory variables.

To account for the number of predictor variables, the adjusted- $R^2$  was used in the current study. This is calculated such that it compensates for the addition of variables in the model. The adjusted- $R^2$  value could increase or decrease with the addition of a variable depending whether the variable adds or does not add to the explanatory power of the model. In this study the adjusted- $R^2$  was used to compare different models, but this by itself is not sufficient to indicate the reliability of a model, because it only indicates how good the fit is. The overall adequacy of a model can be examined by integrating all the tests of validations and methods of selecting predictors to derive a reliable model with sound specifications. A final model can be compiled following a series of steps and iterating these when necessary.

Reporting the statistics of a final model can be obtained from output of the R-Gui or SPSS programmes (the latter was used because of its convenient tables display). In SPSS tables can be used to summarise regression results of an overall model and the model's predictor (or explanatory) variables. These tables include: model summary, analysis of variance (ANOVA), and coefficients. Assuming that we have  $k$  predictor variables,  $N$  observations, goodness of fit and significance measures for the entire model are given by: adjusted- $R^2$ ,  $F$ -ratio( $k, N-(k+1)$ ), and  $p$ -value of the model. The  $F$ -ratio (also referred to as overall  $F$ ) is another indicator of the observed variability in the samples responses; the brackets include the degrees of freedom ( $df$ ) of the regression (effect) and residuals (errors), respectively. The significance of the

*F*-ratio indicates if the model is a significant fit to the data and only indicates whether at least one variable has a significant effect on the outcome variable, but it does not indicate which one is significant (Stevens, 2012).

The coefficients table provides information about the explanatory variables. This table includes unstandardised (*B*) coefficients, standardised (*beta*) coefficients, and statistical significance (*p*-value) (Berkman & Reise, 2012; Simon, 2003). The unstandardised *B* coefficient for a variable, *x*, represents the effect of a one unit increase in a predictor, *x*, on the outcome variable, *y*, holding all other predictor variables constant (Gerstman, 2015). This was used in the current study to present practical interpretations for the relationship between HbA1c and each of the significant predictors; for example, the number of units that is needed to change on a specific scale to predict a change in HbA1c. The standardised *beta* coefficients are the results of a regression where all variables (both predictor and outcome variables) have been converted to z-scores; that is, they are measured in the number of standard deviations from their respective means (Gerstman, 2015). The *beta* coefficient for a predictor variable, *x*, therefore represents how many standard deviations we would expect *y* to increase when *x* increases by one standard deviation. It is useful when the predictors are measured in very different units, and it is also useful as a measure of a comparable effect size (Gerstman, 2015). The current study used *beta* to measure the magnitude of the effect of the predictor variables (having different units) on the outcome variable.

Full results of descriptive and the regression analyses are covered in the next section.

## Results

### Reliability of BIPQ, CIDS, and PedsQL 3.2

The Cronbach's alpha coefficient for the BIPQ was 0.704, suggesting good reliability (see Bland & Altman, 1997; Gliem & Gliem, 2003). The Cronbach alpha coefficient for the CIDS in the current study was 0.923, which represents excellent internal consistency (see Bland & Altman, 1997; Gliem & Gliem, 2003). The total PedsQL had a Cronbach alpha coefficient of 0.922, which suggests excellent internal consistency (see Bland & Altman, 1997; Gliem & Gliem, 2003). Most of the reliability coefficients of the individual scales of PedsQL were also in the acceptable to excellent range (Table 3.1), except for the treatment barrier scale which was just slightly less than 0.7. Cronbach alpha less than 0.7 can be acceptable but needs to be interpreted with caution (Bland & Altman, 1997; Gliem & Gliem, 2003).

**Table 3.1**

*Reliability (internal consistency) of the PedsQL scales*

PedsQL dimension	Cronbach alpha coefficients
Diabetes symptoms	0.888
Treatment Barriers	0.654
Treatment Adherence	0.826
Worry	0.798
Communication	0.795

The above results in this section indicated valid reliability of the BIPQ, CIDS, and PedsQL 3.2 measures. The findings allow proceeding confidently to the next part of the data analyses and interpretation.

## Descriptive Statistics

This section describes both the raw data and preliminary interpretations of observed mean scores, as well as presenting descriptive and explorative analyses on the variables included in the current study.

The mean age was 19.9 ( $SD = 3.0$ ) years. The mean HbA1c was 77 mmol/mol ( $SD = 26$  mmol/mol), which is above the recommended level and is classified in the suboptimal diabetes control range. The majority of youth (66.1%) had unsatisfactory levels of HbA1c, with more than half of those individuals (35.7%) falling in the poor and very poor HbA1c ranges (Table 3.2). Very few individuals (5.4%) achieved an optimal diabetes control.

**Table 3.2**

*A description of type 1 diabetes control in the study population (N=56), defined by HbA1c range*

Diabetes control categories <sup>+</sup>	<i>n</i>	%	HbA1c (mmol/mol)	
			<i>M</i>	<i>SD</i>
Excellent Control (< 50 mmol/mol)	3	5.4%	42	4
Very good control (50-54 mmol/mol)	7	12.5%	52	1
Acceptable but higher than ideal (55-64 mmol/mol)	9	16.1%	59	3
Suboptimal glycaemic control (65-79 mmol/mol)	17	30.4%	71	5
Poor glycaemic control (80-99 mmol/mol)	11	19.6%	88	6
Very poor glycaemic control (>100 mmol/mol)	9	16.1%	123	20

*Note.* <sup>+</sup>Source of categories is NZSSD (2009b)

The mean BIPQ total score was in the middle of the scale with a relatively small deviation from the mean (Table 3.3). This suggests that on average the youth had moderate perceptions of diabetes as a threatening condition. The highest mean score was observed in the timeline subscale ( $M_{\text{score}} = 94.9$ ), which indicates that the youth had a strong perception of the chronicity of the diabetes condition. The lowest mean score was observed in the treatment control (reversed) score, which indicates that the youth perceived treatment as being helpful in controlling their diabetes. The second two lowest means scores, which were well below the total score average, were coherence and personal control (reversed) scores. These mean scores indicated that on average the youth in the current study had a good understanding of their illness and a high level of perceived personal control over their diabetes. The mean scores on the remaining dimensions (consequences of diabetes, concern and emotional representations, and identity) indicated that on average the youth had slightly more threatening views on these subscales compared to the other subscales.

**Table 3.3**

*Mean psychosocial scores of the youth with type 1 diabetes who completed the study questionnaires, N = 56*

Scale	<i>M</i>	<i>SD</i>
BIPQ-Total	50.3	12.0
BIPQ 1-Consequences	60.5	21.2
BIPQ 2-Timeline	94.9	12.0
BIPQ 3- Personal control (reversed)	36.8	22.1
BIPQ 4-Treatment control (reversed)	17.5	18.8
BIPQ 5-Identity	55.7	19.6
BIPQ 6-Concern	61.7	24.4
BIPQ 7-Coherence (reversed)	22.1	20.3
BIPQ 8-Emotions	53.8	27.4
PedsQL-Total	61.1	15.5
PedsQL-Diabetes symptoms	56.7	14.8
PedsQL-Worry	48.7	22.2
PedsQL-Treatment Barriers	69.7	19.1
PedsQL-Treatment Adherence	66.0	21.0
PedsQL-Communication	64.3	23.7
CIDS	75.4	15.9

The total score on the PedsQL 3.2 had a mean score of 61.1. This indicated that they were closer to the higher end of the scale, which suggests having fewer problems associated with diabetes QoL (Table 3.3). All the dimension scores, except worry, were above 50, indicating fewer problems related to diabetes QoL. The lowest mean score ( $M = 48.7$ ) was on the worry scale, which indicated that the youth in the current study on average had problems associated with worrying about diabetes complications. The highest mean score ( $M = 69.7$ ) was on the treatment barriers subscale, which suggested that the youth had the least problems associated with barriers to diabetes treatment (e.g., pain from pricking finger and taking insulin injections, and embarrassment caused by diabetes treatment). The mean score on the CIDS scale was relatively high ( $M = 75.4$ ) – Table 3.3. This suggests that the youth,

on average had strong self-efficacy related to their diabetes self-management.

### **Relationships among variables**

The full interrelationships table can be found in Appendix 3.2. The following descriptions present relationships that met the significance criterion (i.e.,  $p < 0.05$ ) of the bivariate relationships.

#### ***Glycaemic control: HbA1c***

Glycaemic control was significantly associated with several variables. These were: age ( $r = -0.363$ ,  $p < 0.01$ ); BIPQ total score ( $r = 0.295$ ,  $p < 0.05$ ), personal control ( $r = 0.363$ ,  $p < 0.01$ ), and coherence ( $r = 0.282$ ,  $p < 0.05$ ); and PedsQL total score ( $r = -0.268$ ,  $p < 0.05$ ), treatment adherence ( $r = -0.351$ ,  $p < 0.01$ ), and communication ( $r = -0.315$ ,  $p < 0.05$ ). These results suggest that lower HbA1c levels were associated with older age, and increased perceived personal control and understanding of diabetes. In addition, lower HbA1c levels were associated with fewer problems related to treatment adherence and communication. Higher levels of HbA1c were associated with poorer QoL and more negative views on diabetes as a threatening disease.

#### ***Illness perception: BIPQ***

The BIPQ total score had several significant interrelationships with other variables included in the analysis; this is in addition to its significant association with HbA1c. BIPQ was correlated with CIDS ( $r = -0.428$ ,  $p < 0.01$ ), PedsQL total score ( $r = -0.751$ ,  $p < 0.01$ ), and each of the five PedsQL dimensions (see Appendix 3.2). These results suggest that more negative views on diabetes as a threatening disease

are associated with lower levels of self-efficacy and poorer QoL.

The inter-correlations amongst the BIPQ individual subscales presented several significant associations. The BIPQ consequences score was correlated with identity ( $r = 0.434, p < 0.001$ ), concern ( $r = 0.302, p < 0.05$ ), and emotions scores ( $r = 0.529, p < 0.01$ ). This suggested that more perceived consequences of diabetes were associated with a highly perceived symptomatic condition, and higher levels of concern and negative emotions.

Perceived personal control was associated with treatment control ( $r = 0.409, p < 0.01$ ), coherence ( $r = 0.441, p < 0.01$ ), identity ( $r = 0.270, p < 0.05$ ). This suggests that a higher level of perceived control was correlated with more understanding of diabetes and a higher level of perceived treatment control. In contrast, a lower level of perceived control was associated with a highly perceived symptomatic condition.

A higher level of perceived emotions was correlated with higher perceived identity ( $r = 0.377, p < 0.05$ ) and concern ( $r = 0.475, p < 0.01$ ), and lower level of coherence ( $r = 0.325, p < 0.05$ ). The BIPQ timeline scores were not associated with any of the variables.

### ***Self-efficacy: CIDS***

Self-efficacy was significantly associated with personal control, treatment control, and coherence ( $r = -0.528, p < 0.01$ ;  $r = -0.268, p < 0.05$ ;  $r = -0.405, p < 0.01$ , respectively). These relationships suggest that greater self-efficacy in diabetes self-management was associated with higher perceived personal and treatment control, and understanding of illness. Furthermore, self-efficacy in diabetes self-



management was significantly associated with the PedsQL total score, treatment barriers, treatment adherence, and communication ( $r = 0.568$ ;  $r = 0.440$ ;  $r = 0.634$ ;  $r = 0.562$ ;  $p < 0.01$ , respectively). These correlations suggest that higher self-efficacy in diabetes self-management were associated with better overall QoL, and fewer problems with treatment barriers, adherence, and communication.

### ***Quality of Life: PedsQL***

In addition to the mentioned above associations related to the QoL components, the total PedsQL 3.2 score was significantly associated with all of the BIPQ dimensions, except for the BIPQ timeline (Appendix 3.2). The associations were in a negative direction, ranging from  $r = -0.374$  to  $r = -0.598$  ( $p < 0.01$ ). These correlations suggest that higher perceived personal and treatment control, and coherence were associated with better overall QoL. In contrast, higher perceived consequences, identity, concern, and emotions related to diabetes were associated with poorer QoL.

The PedsQL diabetes symptoms scores were significantly associated with BIPQ consequences ( $r = -0.451$ ,  $p < 0.001$ ), personal control ( $r = -0.330$ ,  $p < 0.05$ ), identity ( $r = -0.615$ ,  $p < 0.01$ ), coherence ( $r = -0.285$ ,  $p < 0.05$ ), and emotions ( $r = -0.485$ ,  $p < 0.01$ ). These results suggest that fewer problems related to diabetes symptoms were correlated with higher perceived control, more understanding of diabetes, a lower perceived somatic identity and fewer negative emotions.

The PedsQL treatment barriers score was significantly correlated with most of the BIPQ scores, except timeline and concern. More barriers to treatment were correlated with higher perceived consequence ( $r = -0.461$ ,  $p < 0.01$ ), less perceived

personal ( $r = -0.424, p < 0.01$ ) and treatment control ( $r = -0.461, p < 0.01$ ), more somatic diabetes ( $r = -0.422, p < 0.01$ ), lower level of coherence ( $r = -0.468, p < 0.01$ ), and more perceived negative emotions ( $r = -0.501, p < 0.01$ ).

PedsQL treatment adherence was significantly associated with the majority of BIPQ dimensions except for timeline. Fewer problems associated with treatment adherence were correlated to higher perceived personal and treatment control ( $r = -0.413, p < 0.001$ ;  $r = -0.405, p < 0.01$ , respectively), and more understanding of the illness ( $r = -0.426, p < 0.01$ ). In contrast, more problems in treatment adherence were associated with more perceived consequences ( $r = -0.294, p < 0.05$ ), diabetes as a somatic condition ( $r = -0.389, p < 0.01$ ), more concern ( $r = -0.321, p < 0.05$ ), and negative emotions ( $r = -0.468, p < 0.01$ ).

The PedsQL worry was associated with BIPQ consequences ( $r = -0.285, p < 0.05$ ), concern ( $r = -0.563, p < 0.01$ ), coherence ( $r = -0.325, p < 0.01$ ), and emotions ( $r = -0.473, p < 0.01$ ). More worries about diabetes complications were correlated with higher perceived consequences, lower level of coherence, more concern and negative emotions.

PedsQL communication was significantly associated with BIPQ consequences, personal control ( $r = -0.341, p < 0.05$ ), identity ( $r = -0.289, p < 0.05$ ), coherence ( $r = -0.465, p < 0.01$ ), and emotions ( $r = -0.392, p < 0.01$ ). A higher level of communication was associated with fewer problems with negative emotions, identity, perceived consequences, and higher levels of perceived personal control and coherence.

The five PedsQL dimensions were all significantly interrelated. The results of

the PedsQL interrelationship in general suggest that fewer problems in one of the dimensions was associated with a better QoL outcome on the dimension that it was significantly associated with. As an example, the PedsQL diabetes symptoms score was positively associated with all other PedsQL dimensions: worry ( $r = 0.400, p < 0.01$ ), treatment barriers ( $r = 0.488, p < 0.01$ ), treatment adherence ( $r = 0.454, p < 0.01$ ), and diabetes communication ( $r = 0.400, p < 0.01$ ). These correlations suggest that individuals who experience fewer problems associated with diabetes symptoms also experienced fewer problems associated with worries, treatment barriers and adherence, and diabetes communication.

### **Gender differences**

Independent-samples t-tests were conducted on individual variables, including HbA1c and the questionnaires scores, to assess if there were any gender differences. Comparing females and males revealed that females had poorer QoL associated with diabetes symptoms compared to males ( $t(54) = -2.58, p = 0.013$ ). In addition females perceived diabetes as being more symptomatic compared to males ( $t(54) = 2.01, p = 0.049$ ). Gender differences were not detected in any other variables, including HbA1c, age, and questionnaires scores. Based on the above findings, because there is at least one significant difference according to the gender groups, this variable was included as a potential moderator in the regression model.

### **Regression analysis predictor variables selection**

Selection of the predictor variables of HbA1c for inclusion in the regression analysis involved examining the level of correlation amongst variables. In the current study, because the BIPQ and PedsQL total scores were strongly correlated (i.e., high

linear dependency;  $r = 0.75$ ) the PedsQL total score was replaced by its five dimensions, which represent the aforementioned five QoL constructs: diabetes symptoms, treatment barriers, treatment adherence, worry, and communication. These dimensions had significant associations with BIPQ, but were all less than 0.7 which suggests multicollinearity is relatively less likely to be present; this was further confirmed in the regression model using specific statistical analysis (e.g., VIF). Furthermore, the total BIPQ was included instead of the eight individual items to reduce the number of variables in the model; hence, the five PedsQL were selected and not the eight BIPQ items. Additional investigations were performed including all eight BIPQ items as well as statistically significant terms from the previous analysis.

### **Regression Analysis**

Multiple linear regression models were used to investigate whether there were any relationships between HbA1c and the predictor variables, and to understand variations in HbA1c across the study population and in relation to psychosocial factors. The MLR assumptions were checked. The ratio of the number of cases to predictor variables (56:9 or 6:1) fulfilled the MLR requirements. Scatter plots of the bivariate relationships and the Pearson's correlation coefficients of HbA1c and predictor variables (Appendix 3.3) were then inspected. The strength of correlations of predictors with HbA1c, using absolute values, ranged from low ( $r = 0.087$ ) to medium correlations ( $r = 0.363$ ). The scatter plots and strength of relationships reflected neither obvious departure from linearity nor clear patterns in the bivariate relationships. In addition, there were no indications of potentially strong collinearity amongst variables, because all the Pearson's correlation coefficients values were less than 0.7 (Appendix 3.4). Formal tests of multicollinearity were used to confirm this

and results are presented in this section. Moreover, on the scatter plots, the HbA1c observations at or exceeding 138 mmol/mol were marked as potential outliers (four entries). Suspected outliers were removed from the dataset to re-examine the scatter plots and the Pearson's correlation coefficients. After removing the potential outlier, the  $|r|$  ranged from 0.099 to 0.389 (Appendix 3.5). Further investigations were undertaken to determine this statistically as detailed below.

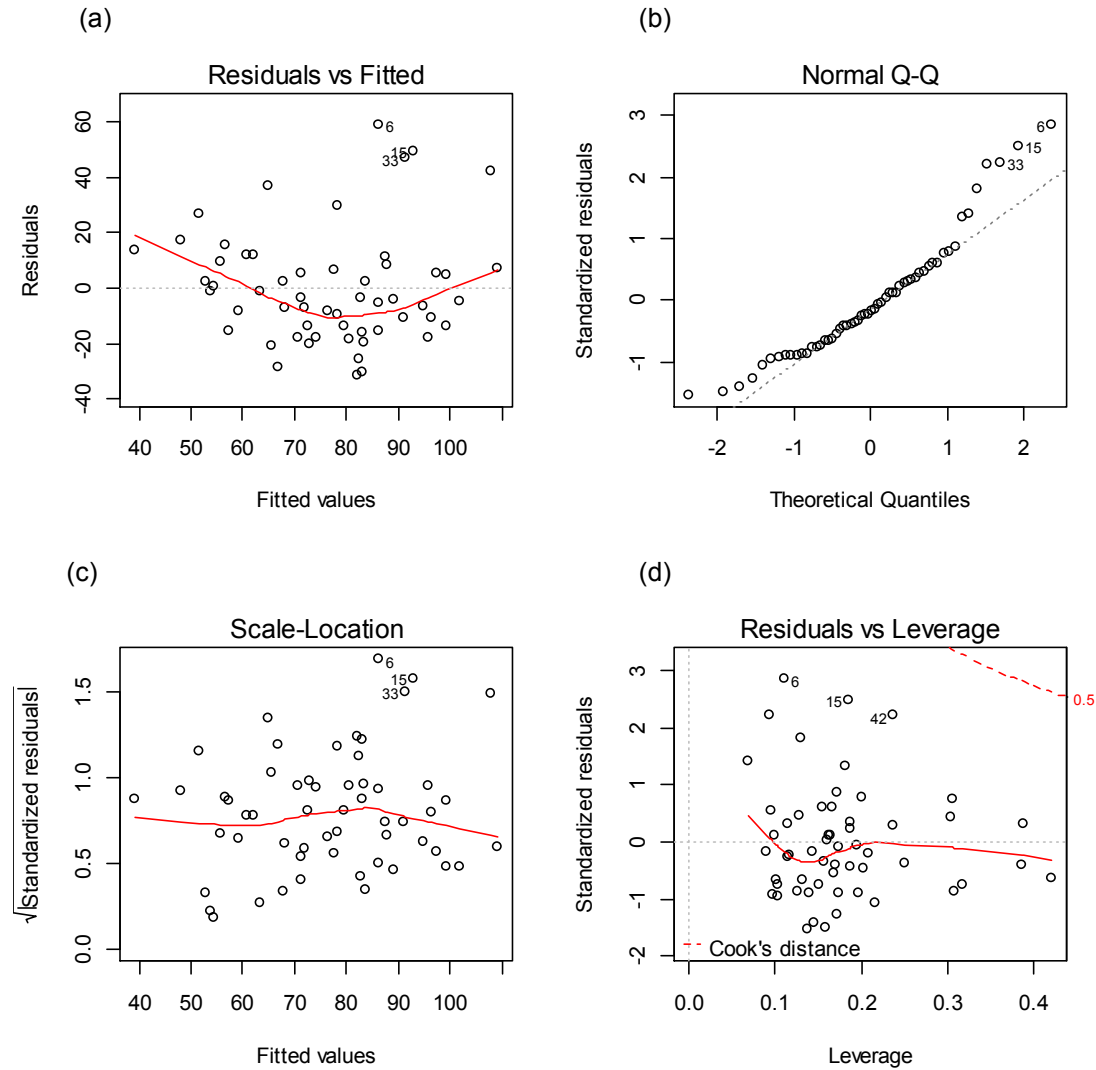
Regression models were fitted, incorporating selected sets of variables, as previously outlined in the methods section. First, a MLR model was built using the Enter method having all variables of interest (i.e., age, BIPQ total score, and the five PedsQL dimensions). Second, models were systematically fitted using the Forward and Backward selections methods. The Enter and Forward selection methods results are presented shortly. The Backward selection method was implemented as a means of cross-checking the results; the results of the Forward and Backward selection methods were essentially the same in this study.

The regression model using the Enter method had a statistically significant  $F$ -ratio:  $F(9,46) = 3.28$ ,  $p = 0.004$ ,  $R^2 = 0.391$ , adjusted- $R^2 = 0.271$ , indicating a statistically significant relationship that explains some of the variation in HbA1c. The effect sizes and statistical significance of the predictor variables in this model are shown in Table 3.4, ranked from strongest to weakest effect sizes. Figure 3.2 shows the diagnostic plots of this model.

**Table 3.4***Summary of the regression model using the Enter method to explain variation in HbA1c, N = 56*

Predictor Variable	<i>B</i>	<i>beta</i>	<i>p</i>
PedsQL-Treatment Adherence	-0.644	-0.527	0.008*
PedsQL-Worry	0.451	0.391	0.007*
CIDS	0.567	0.351	0.040*
Age	-2.497	-0.276	0.030*
PedsQL- Communication	-0.266	-0.246	0.148
BIPQ-Total	0.476	0.222	0.231
PedsQL-Treatment Barriers	0.139	0.104	0.580
PedsQL-Diabetes Symptoms	0.080	0.046	0.767
Gender	1.828	0.035	0.795
$F(9,46) = 3.28, p = 0.004, R^2 = 0.391, \text{adjusted-}R^2 = 0.271$			

*Note.* \* Statistically significant predictors



**Figure 3.2.** Diagnostic plots for the regression model using the Enter method to explain variation in HbA1c,  $F(9,46) = 3.28$ ,  $p = 0.004$ ,  $R^2 = 0.391$ , adjusted- $R^2 = 0.271$ . The diagnostic plots check for (a) model misspecification: the residuals should be independent of the fitted values, (b) normality of the residuals: the theoretical and the observed quantiles should coincide, (c) homogeneity (constant variance of the residuals), (d) outliers (points with high leverage and high residuals).

The flagged outliers (4 observations) in Figure 3.2 plots were individually examined. It was determined that they belonged to the subgroup  $\text{HbA1c} \geq 138$  mmol/mol. A model was implemented using the Enter method excluding these outliers, to compare it to the previous model of Table 3.4. The new model (without the outliers) also had a statistically significant  $F$ -ratio:  $F(9,42) = 3.43$ ,  $p = 0.003$ ,  $R^2 =$

0.423 adjusted- $R^2 = 0.3$ . The model summary is presented in Table 3.5, and Figure 3.3 presents the diagnostic plots for this model. After removing the outliers, the results changed considerably. This included changes in the statistical significance, sign of *betas*, and effect sizes, which indicated that the outliers had an influence on the model and reliability of results.

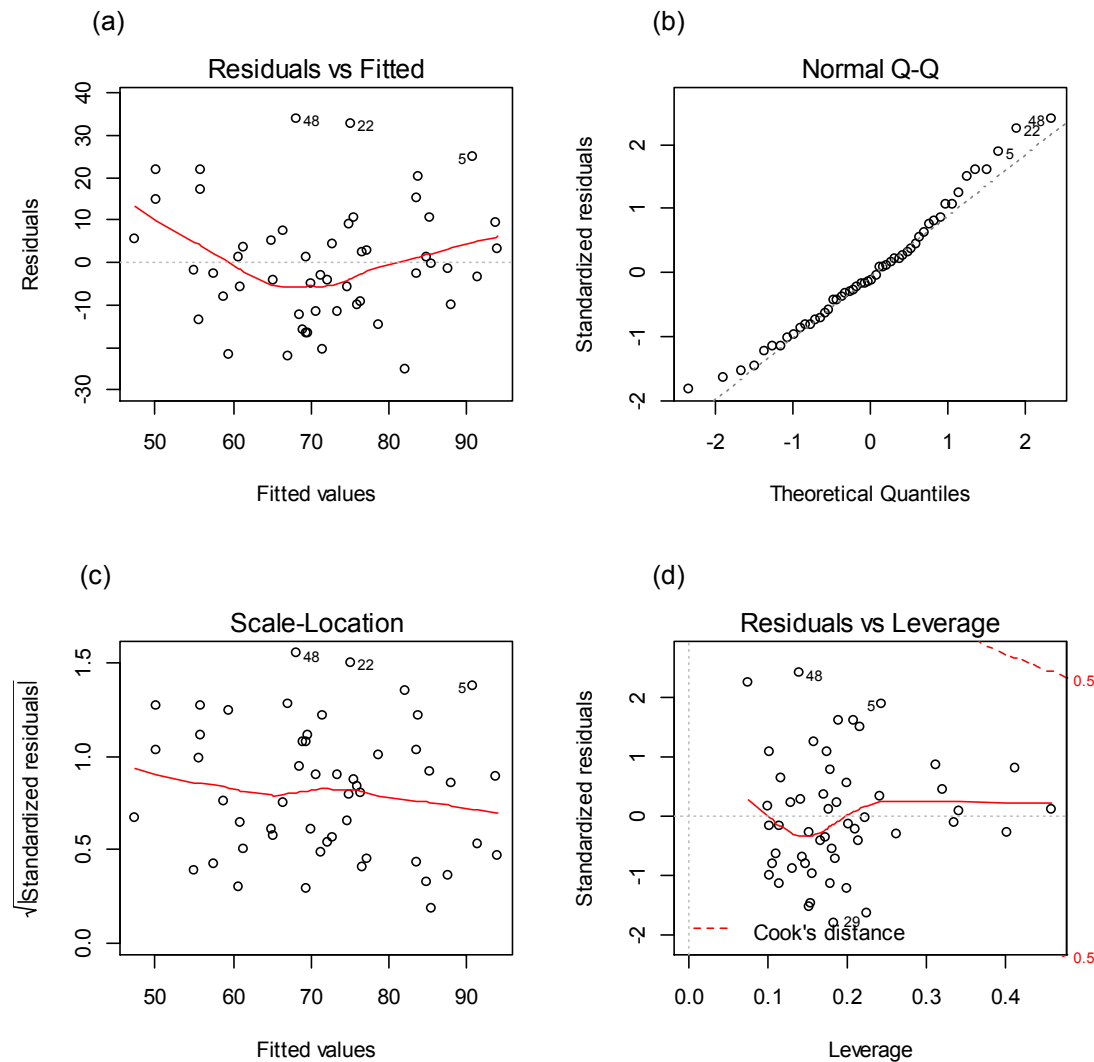
**Table 3.5**

*Summary of the regression model using the Enter method and after removing potential outliers to explain variation in HbA1c, N = 52*

Predictor Variable	<i>B</i>	<i>beta</i>	<i>p</i>
PedsQL-Worry	0.381	0.450	0.003*
BIPQ-Total	0.665	0.447	0.023*
Age	-1.977	-0.314	0.015*
PedsQL-Treatment Adherence	-0.302	-0.336	0.101
CIDS	0.240	0.217	0.223
PedsQL-Treatment Barriers	0.186	0.199	0.297
PedsQL-Communication	-0.121	-0.160	0.351
Gender	-2.159	-0.059	0.669
PedsQL- Diabetes Symptoms	0.033	0.028	0.863
$F(9,42) = 3.43, p = 0.003, R^2 = 0.423, \text{adjusted-}R^2 = 0.3$			

*Note.* \* Statistically significant predictors





**Figure 3.3.** Diagnostic plots for the regression model using the Enter method to explain variation in HbA1c,  $F(9,42) = 3.43$ ,  $p = 0.003$ ,  $R^2 = 0.423$ , adjusted- $R^2 = 0.3$ . The diagnostic plots check for (a) model misspecification, (b) normality of the residuals, (c) homogeneity, and (d) influential outliers.

To further assess the stability of Table 3.5 model, the new set of potential outliers in Figure 3.3 were checked and removed; these outliers did not belong to a subgroup. The new model had very small changes to the  $p$  values and effect sizes, and no changes to sign of  $\beta$ s or the overall results; hence, indicating the stability of the model in Table 3.5. Multicollinearity was also checked in the Table 3.5 model, all VIF values were less than 3. The normality and linearity assumptions were checked in Figure 3.3, and these were all found to be acceptable. The

*influence.measures* checks were also acceptable. The current model therefore complied with the MLR assumptions and can be used as an explanatory model.

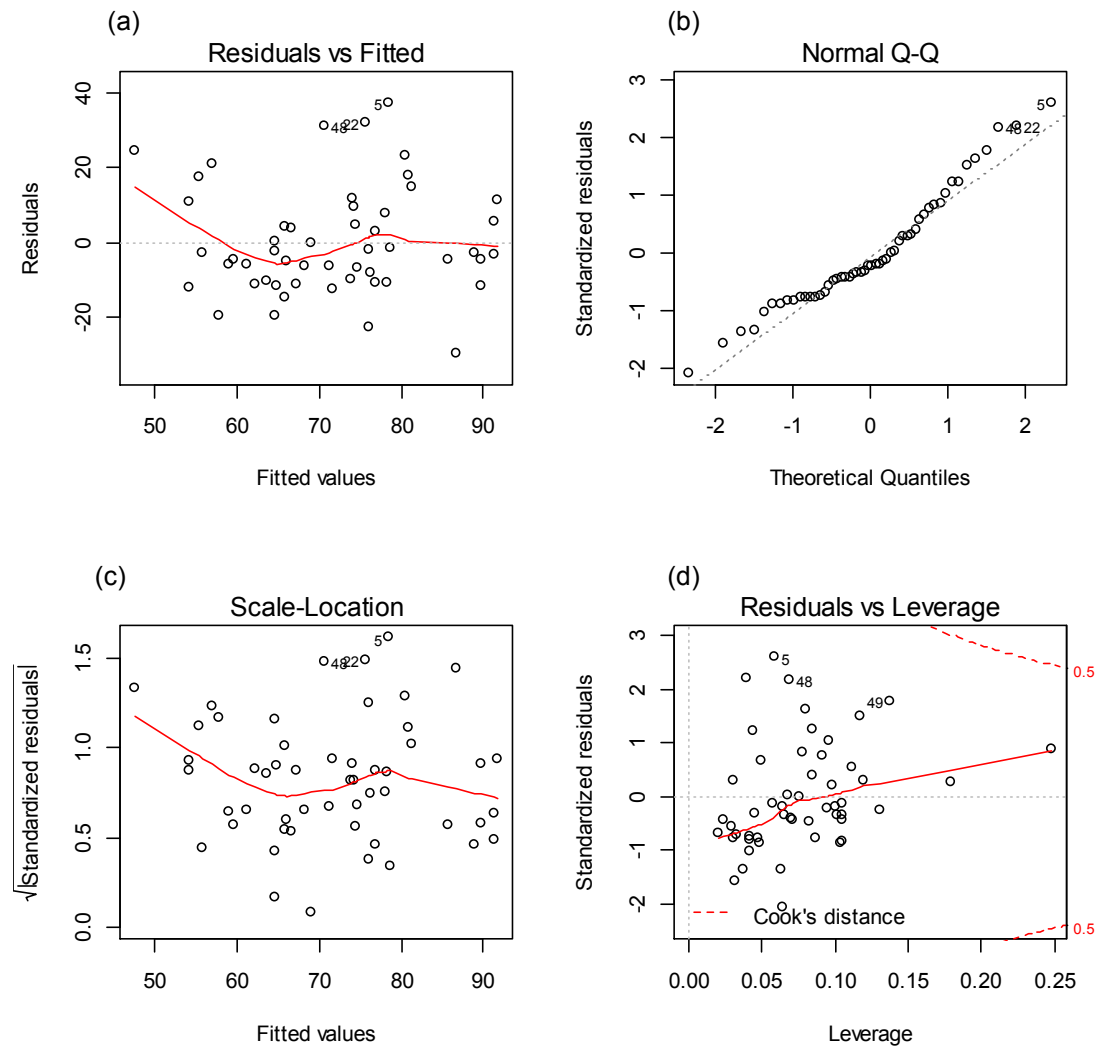
The model of Table 3.5 was simplified further by using the Forward selection method. A model with the highest adjusted- $R^2$  (0.329) was selected:  $F(3,48) = 9.35$ ,  $p < 0.0001$ ,  $R^2 = 0.369$ . A summary of this model is presented in Table 3.6, and Figure 3.4 presents the diagnostic plots. In Figure 3.4, outliers were flagged. These were inspected and were removed to check their impact on the model, the model remained stable (overall results are similar). The BIPQ total score, PedsQL-Worry score, and age had statistically significant relationship with HbA1c, Table 3.6. The combination of these variables explain 36.9% of the variance in HbA1c for values less than 138 mmol/mol. Threatening views about diabetes (i.e., high BIPQ total score), less worries about diabetes complications, and younger age were associated with high HbA1c.

**Table 3.6**

*Summary of the regression model using the Forward selection method to explain variation in HbA1c,  $N = 52$*

Predictor Variable	<i>B</i>	<i>beta</i>	<i>p</i>
BIPQ-Total	0.727	0.489	0.001*
PedsQL-Worry	0.343	0.405	0.003*
Age	-2.095	-0.332	0.006*
$F(3,48) = 9.35, p < 0.001, R^2 = 0.369, \text{adjusted-}R^2 = 0.329$			

*Note.* \* Statistically significant predictors



**Figure 3.4.** Diagnostic plots for the regression model using the Forward selection method to explain variation in HbA1c,  $F(3,48) = 9.35$ ,  $p < 0.001$ ,  $R^2 = 0.369$ , adjusted- $R^2 = 0.329$ . The diagnostic plots check for (a) model misspecification, (b) normality of the residuals, (c) homogeneity, and (d) influential outliers.

### The BIPQ subscales and HbA1c

A similar procedure using the above methods was followed to explore the relationship between HbA1c and individual BIPQ subscales. The contribution of the BIPQ subscale in explaining the variance of HbA1c was examined. A model was fitted that comprised the eight BIPQ subscales and the significant terms found in the

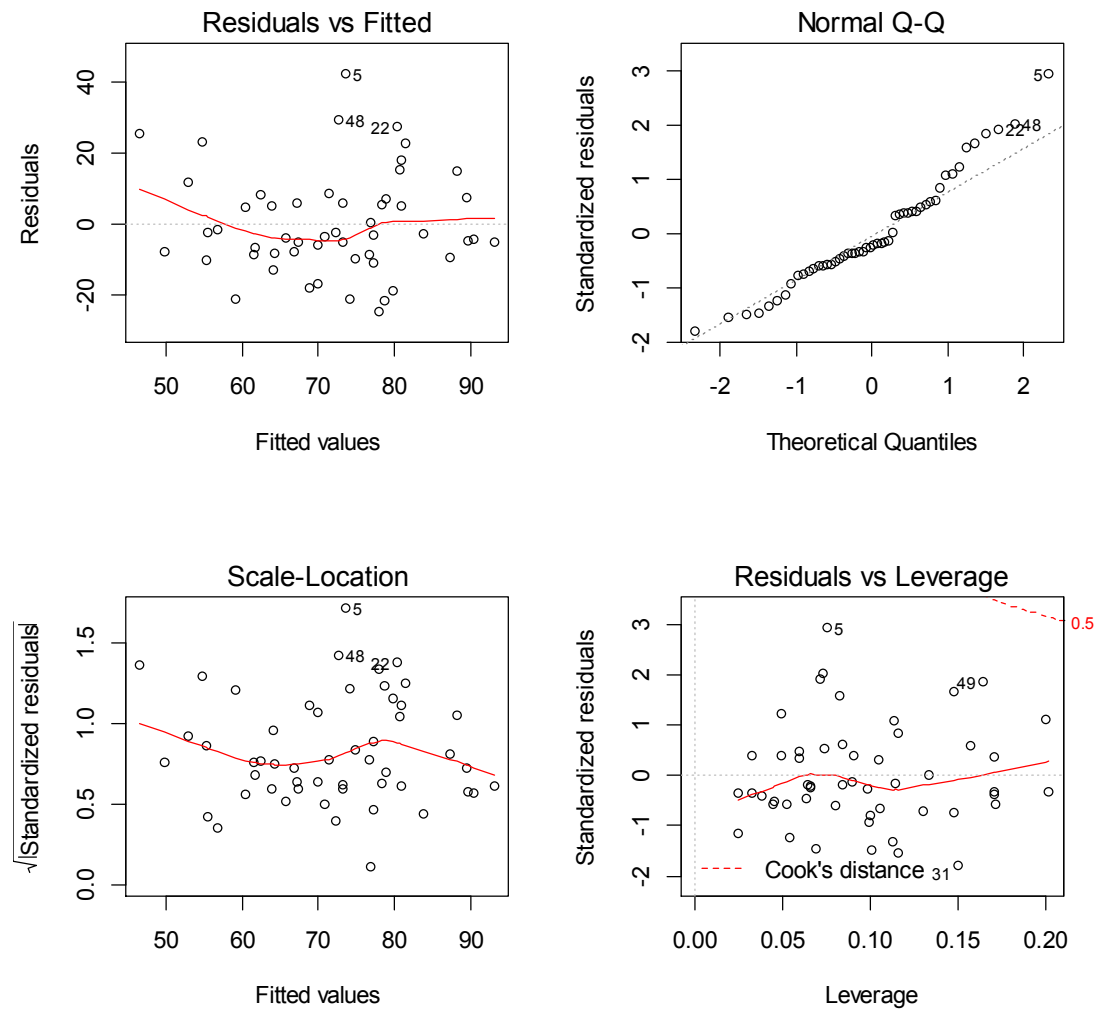
previous analysis (i.e., age and PedsQL-Worry). A set of outliers ( $\text{HbA1c} \geq 138$  mmol/mol) found in previous analysis were excluded from this model because of its influence on the reliability and validity of results. The Forward selection method was used to simplify further the model (see Table 3.7 and Figure 3.5). Other potential outliers were detected and inspected closely – the model remained stable after removing these (and the overall results are similar). Multicollinearity was also checked – all VIF values were less than 2. The fitted model ( $F(4,47) = 6.93$ ,  $p < 0.001$ ,  $R^2 = 0.371$ , adjusted  $R^2 = 0.318$ ) satisfied the four principal assumptions for linear regression: linearity, homoscedasticity, independence and normality. Perceived personal control, concern, age, and worry were significantly associated with HbA1c (Table 3.7). The combination of these variables explained 37.1% of the variation in HbA1c. The results suggest that high perceived personal control and low perceived concern were associated with low HbA1c levels. Age and worry had similar relationships with HbA1c to that presented in the previous section.

**Table 3.7**

*Summary of the regression model using the Forward selection method to explain variation in HbA1c,  $N = 52$*

Predictor Variable	<i>B</i>	<i>beta</i>	<i>p</i>
Age	-2.816	-0.447	0.001*
PedsQL-Worry	0.336	0.397	0.006*
BIPQ 6-Concern	0.245	0.313	0.033*
BIPQ 3-Personal control (reversed)	0.260	0.293	0.019*
$F(4,47) = 6.93$ , $p < 0.001$ , $R^2 = 0.371$ , adjusted- $R^2 = 0.318$			

*Note.* \* Statistically significant predictors



**Figure 3.5.** Diagnostic plots for the regression model using the Forward selection method to explain variation in HbA1c,  $F(4,47) = 6.93$ ,  $p < 0.001$ , adjusted- $R^2 = 0.318$ . The diagnostic plots check for (a) model misspecification, (b) normality of the residuals, (c) homogeneity, and (d) influential outliers.

### Worry scale and HbA1c

The worry scale comprised of three questions representing worries about the complications of diabetes: *going low*, *going high*, and long-term complications. A total score on the scale contributed significantly to explaining the variation in HbA1c. Regression analysis was carried out to explore the contribution of individual worry questions in explaining HbA1c. A similar procedure for validating the model,

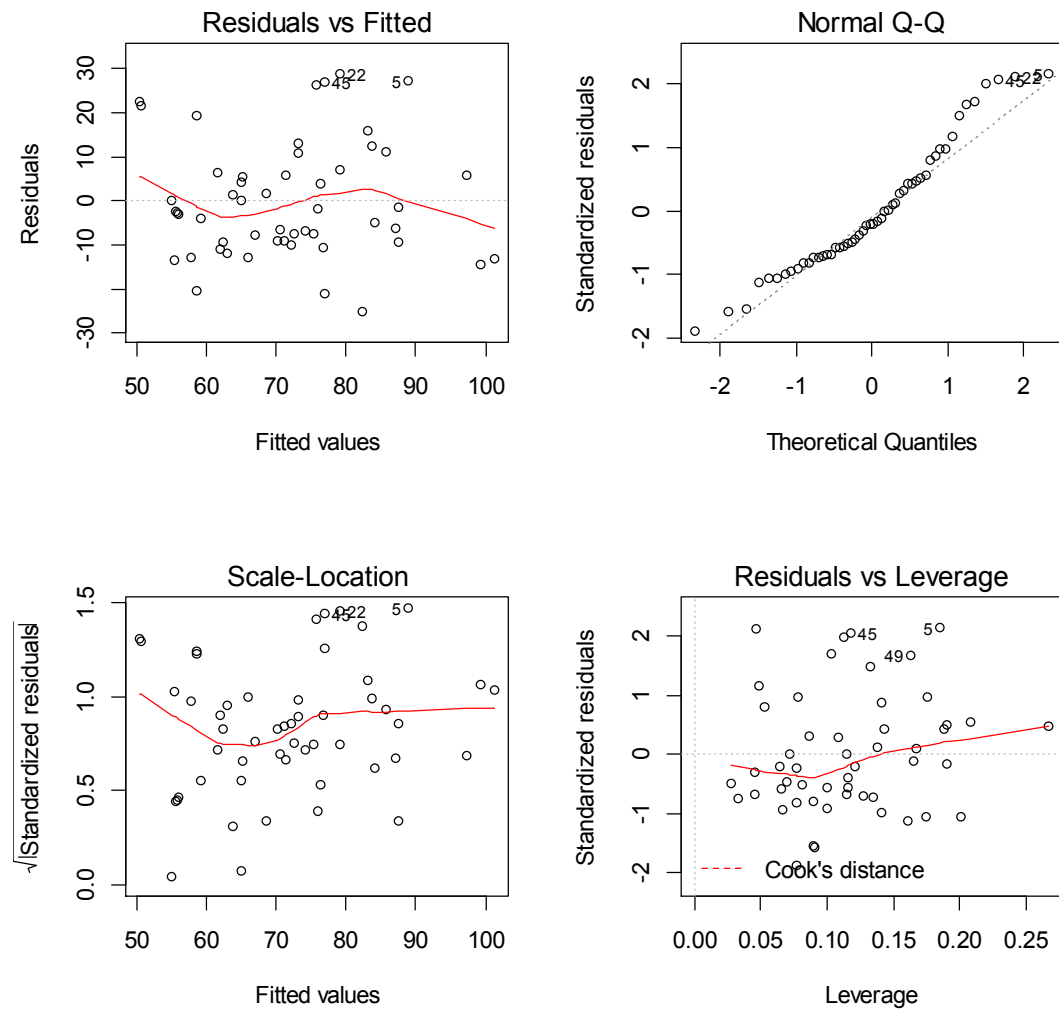
as outlined in the above sections, was carried out. The influential set of outliers,  $HbA1c \geq 138$ , was removed. Table 3.8 presents results of the worry scale questions and HbA1c relationships,  $F(5,46) = 8.08$ ,  $p < 0.001$ ,  $R^2 = 0.467$ , adjusted- $R^2 = 0.41$ . The model remained stable with the removal of further outliers. The four principal assumptions for linear regression were satisfied (Figure 3.6): linearity, homoscedasticity, independence and normality. In addition to age and BIPQ total score, *going low* was significantly associated with HbA1c, Table 3.8. The results suggest worrying more about *going low* is associated with lower HbA1c.

**Table 3.8**

*Summary of the regression model using the Enter method to explain variation in HbA1c,  $N = 52$*

Predictor Variable	<i>B</i>	<i>beta</i>	<i>p</i>
Worry: <i>going low</i>	0.336	0.396	0.019*
BIPQ-Total	5.272	0.354	0.010*
Age	-2.094	-0.332	0.004*
Worry: long-term complications	-0.140	-0.215	0.145
Worry: <i>going high</i>	-0.140	0.207	0.212
$F(5,46) = 8.08$ , $p < 0.001$ , $R^2 = 0.467$ , adjusted- $R^2 = 0.410$			

*Note.* \* Statistically significant predictors



**Figure 3.6.** Diagnostic plots for the regression model using the Enter method to explain variation in HbA1c,  $F(5,46) = 8.08$ ,  $p < 0.001$ ,  $R^2 = 0.467$ , adjusted- $R^2 = 0.41$ . The diagnostic plots check for (a) model misspecification, (b) normality of the residuals, (c) homogeneity, and (d) influential outliers.

## Discussion

The mean HbA1c (77 mmol/mol) in the current study was above the recommended level and in the suboptimal glycaemic control range, but is comparable to the mean HbA1c values found in other studies that had a similar age range (e.g., Griva et al., 2000; Hackworth et al., 2013; McGrady et al., 2014). A large percentage (82.2%) of youth in the current study had HbA1c levels higher than recommended, with more than half of the youth (66.1%) having HbA1c > 65 mmol/mol, and only a small percentage (5.4%) in the excellent control range. These results showed a similar pattern to that found in the audit study in Chapter 2, with the vast majority of youth not meeting the minimally acceptable HbA1c targets.

Poor diabetes control (high HbA1c) is associated with higher risks for diabetes-related complications, increased likelihood of hospital admissions, and poorer QoL (Angus & Waugh, 2007; Levine et al., 2001; Palta et al., 1997). This means that more than 60% of youth with type 1 diabetes in the CDHB catchment area, in the present study cohort, were vulnerable to these risks, and that further action is required to facilitate improvements in diabetes control. This may be achieved through, for example, interventions specifically designed to suit the unique needs of youth with type 1 diabetes. To identify the needs of youth that can influence diabetes outcomes, an understanding of their diabetes-related attributes is necessary. This includes understanding key psychosocial characteristics associated with diabetes control.

The current study explored psychosocial characteristics of youth (15-24 year olds) with type 1 diabetes and the relationships between these characteristics and



HbA1c. The results show that lower HbA1c was associated with older age. Furthermore, perception of diabetes as a threatening condition was related to poorer diabetes control. Higher levels of perceived personal control and understanding of diabetes were associated with lower HbA1c. In addition, better overall diabetes-specific QoL and fewer problems associated with diabetes-related communication (e.g., with health professionals or other people) and adherence to treatment were associated with better glycaemic control. All of these findings were as expected and are consistent with previous research (Al-Hayek et al., 2014; Bazzazian & Besharat, 2010; Fortenberry et al., 2014; Huggard, 2009; Laffel et al., 2014; McGrady et al., 2014; Pereira et al., 2011; Pinhas-Hamiel et al., 2014). Furthermore, the bivariate relationships in the current study had mostly moderate strength associations, with a maximum Pearson's correlation  $|r| = 0.363$ , which was also similar to that reported in the previous research.

A series of regression analyses in the current study presented consistent and supporting evidence of the role of some of the psychosocial factors (worry and illness perceptions) in predicting glycaemic control. A new understanding emerged from interpreting the relationships of the significant psychosocial factors with HbA1c. These relationships are discussed after a summary and interpretation of the results is outlined.

The results of the exploratory regression analysis showed that nine predictors together explained 42.3% of the variation in HbA1c. The predictors were: age, gender, illness perception, self-confidence in diabetes self-care, diabetes symptoms, worry about diabetes, treatment barriers, treatment adherence, and communication. A combination of these variables has not been presented in previous research; hence,

data on a similar model are not available. Significant predictors of HbA1c in this model included: age, illness perception and worry; the remaining variables had non-significant ( $p > 0.05$ ) relationships with HbA1c.

The nine predictors' model was further simplified using systematic selection methods, which resulted in an 'optimal' model with the abovementioned three significant predictors (age, illness perceptions, and worry). Consistent with the full model findings, higher age predicted lower HbA1c, higher scores on the BIPQ predicted higher HbA1c, and more frequent worry about diabetes complications predicted lower HbA1c. The former two findings were generally consistent with previous research (Griva et al., 2000; Pereira et al., 2011; Pinhas-Hamiel et al., 2014), but the worry finding diverted from what was expected. This is discussed shortly. The simplified model in the current study explained 36.9% of variation in HbA1c. The BIPQ contributed the most (17.7%) to explaining the HbA1c variation, followed by age and worry (12.9% and 6.2%, respectively).

The current study further explored which particular illness representations contributed significantly to the HbA1c variation. In addition to age and PedsQL-Worry, two of the BIPQ subscales were found to significantly contribute to HbA1c. These were *concern* and *personal control*, contributing respectively 3.5% and 10.1% to the variance of HbA1c. Higher perceived personal control was associated with lower HbA1c levels, and more perceived concern was associated with higher HbA1c. These results were consistent with the general trend found in previous research (Harvey & Lawson, 2009). Griva et al. (2000), using the IPQ instrument, showed that 12.2% of the variance in HbA1c was significantly explained by perceived consequences and identity. An analysis of a total score was not available in the study

by Griva et al. (2000); nonetheless, the overall findings support the role of illness beliefs in predicting HbA1c.

There have been very few studies investigating the role of QoL as a predictor of HbA1c. The study by Skinner et al. (2006) used the diabetes-specific QoL and found that symptom impact, future worries, and impact on activities contributed 5.2% to the variance of HbA1c and that higher HbA1c was associated with poorer QoL. Reid et al. (2013) found that the overall QoL contributed 14% of the variance in glycaemic control; individual dimensions analysis was not presented in this study. The results in the Reid et al. (2013) study suggested that lower QoL was associated with higher HbA1c levels ( $\beta = -0.425, p < 0.01$ ). Pereira et al. (2011) also found that QoL was significantly correlated with HbA1c ( $\beta = 0.244, p < 0.05$ ); higher HbA1c was associated with poorer QoL.

A significant contribution from a QoL dimension was also found in the current study. Worry about diabetes complications explained 6.2% of the variance in HbA1c. A further exploration of the worry scale revealed that worrying about *going low* was a significant term contributing 13.7% to explaining HbA1c. That is, contrary to previous research findings, the current study found that more worries about diabetes complications (specifically worrying about *going low*) were associated with better diabetes control. There is, however, one other study that had a similar finding (Tulloch-Reid & Walker, 2009). Tulloch-Reid and Walker (2009) found that their good diabetes control group (HbA1c < 7%) had more worry and anxiety levels compared to the poor control group in Jamaican youth with type 1 and type 2 diabetes. However, when controlling for age in regression analysis (the mean age was 19 years old), the relationship between HbA1c (outcome measure) and

worry/anxiety (predictor variable) became non-significant. Furthermore, the worry and anxiety being measured in the study by Tulloch-Reid and Walker (2009) represented a more general worry construct, measuring concern about future and life stresses and money matters.

Previous research has investigated *worry* as a dimension within QoL, rather than evaluating the influence of worry on its own in explaining HbA1c. This relationship has potential clinical implications, and therefore, it is recommended that this be researched further. This seems particularly important given that the current study also found that perceptions of diabetes as a threatening disease play a role in predicting HbA1c; greater perceptions of diabetes as threatening could predict higher HbA1c.

The current study findings provide a new understanding of the importance of balancing worries about diabetes complications and perception on diabetes as a threatening condition. That is, the more frequently youth worry about diabetes complications, the more likely it is that HbA1c will be lower. Conversely, with more overall threatening views of diabetes and greater concern about diabetes, HbA1c is likely to be higher. This could have clinical implications for assessing and carefully handling worries about complications and negative views on diabetes.

Further research is needed to examine these relationships. Such research could clarify the association between HbA1c and worry using, for example, a longitudinal study design and structural equation modelling could be used to investigate the significance of different paths associated to HbA1c and worry by direct and mediational effects associations. The paths might include measures related

to hypoglycaemia to reflect the *going low* dimension, such as fear of hypoglycaemia and frequency of hypoglycaemic episodes. Hoey et al. (2001) showed that adolescents who had at least one severe hypoglycaemic episode in the previous 3 months were more worried than those who had not had hypoglycaemic episodes. The Hoey et al. (2001) results, however, also showed that lower HbA1c was associated with fewer worries. The lack of studies in this area and the inconsistency in results of the relationship between HbA1c and worry, given the importance of the clinical implications of findings, encourages further investigations.

In addition to the above interpretations, relationships found amongst the current study variables can be discussed from a different perspective – results from the regression output can be interpreted as follows. Referring to the simplified model in Table 3.6, one unit change (say an increase) in the BIPQ scale corresponds to an increase of 0.7 mmol/mol in HbA1c, which means an increase of 7 mmol/mol for a shift of 10 points on the transformed BIPQ scale. This corresponds to a one point shift on the original Likert scale. A change of at least 5 mmol/mol in HbA1c is considered clinically significant and can be associated with a reduction or increase in the risk for diabetes complications (Little, Rohlfing, & Sacks, 2011; Urrechaga, 2012). For this reason, it could be clinically important to monitor youths' views about diabetes as a threatening (or benign) condition. The *personal control* and *concern* subscales follow a similar pattern, but with a higher level of change required in the score to achieve movement on the HbA1c scale. These two factors require at least 20 points shift on the transformed scale to make a change in HbA1c levels; that is, on the Likert scale moving two points up or down the scale is associated with a significant HbA1c change.

One unit change (e.g., increase) on the total score of the worry subscale corresponds to a 0.3 change in HbA1c in the same direction (i.e., increase). From a clinical perspective this might be considered insignificant. However, if we move, say 25 units on the 0 to 100 worry scale, the HbA1c is likely to change by about 7.5 mmol/mol, which then is a clinically significant change. The above units belong to the linearly transformed scale (i.e., 0 to 100) and to translate this on the original scoring scale (i.e., five scores from 0 to 4) one unit change on the worry subscale might have a significant effect on HbA1c levels. The *going low* scale has a similar trend to that of the overall score; a one score shift on the Likert scale is associated with a significant change in HbA1c level. The above findings need to be further investigated by replicating the current study longitudinally, and possibly by using other instruments that include a measure of worries in relation to diabetes complications.

Research shows that other predictors such as treatment adherence and self-confidence in diabetes self-management may explain some of the variation in HbA1c (Griva et al., 2000; Iannotti et al., 2006; Johnston-Brooks et al., 2002). In the current study, statistically significant results for both treatment adherence and self-confidence were not detected. The bivariate relationship of treatment adherence and HbA1c had a moderate correlation strength but was not significant ( $r = -0.271$ ); whereas the CIDS correlation with HbA1c was weak ( $r = -0.099$ ) and also statistically insignificant. In the regression model, both treatment adherence and CIDS remained as non-significant contributors in explaining HbA1c when controlling for the effect of the other predictor variables. A study by Griva et al. (2000) found that stronger confidence and more adherence to diabetes self-

management are related to better diabetes control in mediational relationships, hence, models exploring mediational relationships may reveal more information on self-efficacy and diabetes control in youth.

Limitations of this study include the response rate of the completed questionnaires. A larger sample might potentially have led to the detection of other significant associations of variables in relation to HbA1c. Given the total population of CDHB youth with type 1 diabetes was 248 it was unlikely that a large sample size would be obtained. A significant challenge to this research were the effects of the 2011 Canterbury earthquakes which caused many people to move houses, resulting in 26 *invalid addresses* and *return to sender* letters; this would have contributed to the smaller sample size. In addition to this, the homogeneity of the sample is another limitation, in that only CDHB youth were part of the current study. The sample size and inclusion of youth from one region within New Zealand limits the generalisability of results.

Another limitation of this study was using strict systematic methods to build models. The systematic methods used had their advantages in making it possible to select a valid model based on efficient criteria, but with the disadvantage of the possibility of missing an optimum model. Nonetheless, it was practically not possible to build and validate all combinations of models. The main aim of the study was to explain the variation in HbA1c in relation to the psychosocial characteristics of youth with type 1 diabetes, whilst meeting requirements for the selected statistical analysis tests.

Finally, the built models also have the limitation of only explaining HbA1c

less than 138 mmol/mol. Observations equal to or more than 138 mmol/mol were statistically determined as influential outliers and were excluded from the models. These might potentially fit a different model and have different outcomes. Future directions might include investigating models with a larger population and *N* sample, and with higher numbers in the extremely poor diabetes control subgroup.

In conclusion, the hypotheses of the present study were supported, with the two exceptions for the relationship of worry and self-efficacy with HbA1c. Youth with type 1 diabetes residing in Canterbury follow a similar trend to youth in other countries in terms of their descriptive psychosocial characteristics and HbA1c. Threatening views of diabetes were associated with higher HbA1c levels and poorer QoL was associated with higher HbA1c. In addition, diabetes control can be significantly explained by a combination of psychosocial constructs including cognitive and emotional representations, as well as diabetes-specific QoL. There was, however, no significant relationship between diabetes-specific self-efficacy beliefs and HbA1c in this study. Furthermore, the worry construct had an interesting association with HbA1c (more worry about diabetes complications were correlated with lower HbA1c), which was different from the expected general trend. The relationships presented in this study added to existing research and bridged some of the gaps in knowledge. In addition, more research questions emerged as a result of these study findings – particularly pertaining the HbA1c and worry relationship.

This study constituted a platform for the next study, presented in Chapter 4, by providing information specific to CDHB youth. The current study data served as a normative sample, which was used to guide the next study analysis, involving the psychosocial measures. These were used as a secondary outcome measure to evaluate



the efficacy of a Motivational Interviewing intervention for youth with type 1 diabetes.

# Chapter 4

## *MI Intervention*

*Evaluation of the efficacy of  
Motivational Interviewing in improving  
diabetes control, adherence, and  
psychosocial functioning in youth with  
type 1 diabetes*

## **CHAPTER 4: MOTIVATIONAL INTERVIEWING INTERVENTION**

### **Introduction**

This chapter presents a study of a Motivational Interviewing (MI) intervention trial with youth with type 1 diabetes. The organisation of this chapter is as follows. A literature review is presented with an overview and general background on diabetes interventions for youth with type 1 diabetes. A description of MI and a review of literature on MI in diabetes interventions are then presented, and then a literature review on MI interventions with youth with type 1 diabetes. The literature review section is followed by a section on the significance, specific aims, and hypothesis of the current research. This chapter also describes the methodological basis related to the study design, participants, measures, and data collection, entry and analysis. Interpretation of the results and discussion concludes the chapter.

### **Overview of Diabetes Interventions**

Youth with type 1 diabetes face persisting challenges associated with managing diabetes (Borus & Laffel, 2010; Hamilton & Daneman, 2002; Pinhas-Hamiel et al., 2014). The daily medical and self-management routine is demanding and requires consistent self-regulation to achieve the recommended targets (Borus & Laffel, 2010). Youth with type 1 diabetes, especially those with poorly controlled diabetes, may require interventions (e.g., medical, behavioural, or psychosocial) to assist improving diabetes outcome (Hood, Rohan, Peterson, & Drotar, 2010).

There has been extensive research investigating interventions for youth with diabetes (Hampson et al., 2000; Hood et al., 2010; Winkley, Landau, Eisler, &

Ismail, 2006). The complexity and combination of factors involved in diabetes management, and individuals unique needs, make it challenging to develop effective interventions that will work for all youth. Meta-analyses of diabetes interventions report a small to medium effect on diabetes outcomes, such as HbA1c, in youth with type 1 diabetes (Hampson et al., 2000; Winkley et al., 2006). Although these effects are only modest they still suggest that interventions have a role in reducing some of the impact of diabetes and the high risk of complications for those with poor diabetes control (Hood & Nansel, 2007).

Different types of interventions have been developed to facilitate effective diabetes management, and thereby improve glycaemic control, for youth with type 1 diabetes. These include family-based, group-based, and individual-based interventions; and may incorporate psychosocial, behavioural, motivational, and didactic intervention components (Plante & Lobato, 2008). In family-focused interventions, parents (in the current thesis this also refers to guardians) are directly involved in attending and participating in the intervention sessions and procedures (Anderson, Svoren, & Laffel, 2007; Plante & Lobato, 2008). Group-based and individual-based interventions can involve parents indirectly or directly in the intervention, depending on the study design and procedures (e.g., Anderson et al., 2007; Plante & Lobato, 2008; Silverman, Haines, Davies, & Parton, 2003).

Although research emphasises the importance of parental involvement and the sharing of responsibility for diabetes management in children and adolescents with type 1 diabetes, research also suggests that the degree of this involvement varies and that it declines as the young person gets older (Hanna & Guthrie, 2003). It is expected that this involvement vanishes in the transitioning to adulthood. Youth

increasingly seek autonomy and independence in diabetes-related tasks and decision making, as they do in other areas of their lives (Comeaux & Jaser, 2010). Increased independent decision-making in relation to diabetes management was found to improve metabolic control (Hanna & Guthrie, 2003). Diabetes interventions for adolescents can facilitate gaining skills that are necessary for making adequate diabetes-related decisions, which can lead to achieving improved glycaemic control (Klok, Sulkers, Kaptein, Duiverman, & Brand, 2009; Ott et al., 2000). In addition, because their parent(s) may have assumed much of the responsibility for their diabetes management, adolescents may lack knowledge and experience at earlier stages of their lives about diabetes, and improved diabetes control can be achieved through building self-efficacy and competence in diabetes management (Klok et al., 2009; Ott et al., 2000).

Research shows interventions can have a positive influence on behavioural and psychosocial factors that have been found to affect diabetes management and QoL in youth (Harvey, 2015; Hood et al., 2010; Murphy, Rayman, & Skinner, 2006; Savage, Farrell, McManus, & Grey, 2010; Urban, Berry, & Grey, 2004). Several reviews have evaluated the effectiveness of diabetes interventions (educational, psychosocial, and behavioural) for youth with type 1 diabetes. A review by Urban et al. (2004) reported that improvements in metabolic control, self-efficacy, diabetes stress, and QoL were demonstrated as a result of psychosocial interventions.

However, Urban et al. (2004) also found inconsistent evidence for education interventions as a means of improving metabolic control. Savage et al. (2010) suggested that education interventions are less effective than psychosocial interventions. A review by Murphy et al. (2006) suggested that none of the

educational interventions on its own has been shown to be effective for youth with poorly controlled diabetes. These findings suggest that interventions that target factors other than increasing knowledge are necessary, especially for youth with poor diabetes control.

A review by Hood et al. (2010) found that multi-component interventions that target psychosocial factors (e.g., emotional and social factors) were effective in improving metabolic control. The same study also found interventions that only focused on direct behavioural processes (e.g., increase frequency of SMOBG) and neglected targeting other factors (e.g., illness perceptions and self-efficacy) were unlikely to have an impact on metabolic control (Hood et al., 2010).

The above findings emphasise the need to develop interventions that target a combination of factors (e.g., psychosocial and behavioural). In addition, interventions that can foster self-efficacy, autonomy, and active engagement of youth in managing their diabetes are likely to promote positive diabetes outcomes (Harvey, 2015). Motivational Interviewing is an intervention that meets these criteria and has attributes which make it a potentially suitable and effective intervention for youth (Miller & Rollnick, 2013; Welch, Rose, & Ernst, 2006).

Motivational Interviewing has been applied to a range of health behaviours including dietary behaviours, exercise promotion, oral health, and diabetes (Gayes & Steele, 2014; Lundahl, Kunz, Brownell, Tollefson, & Burke, 2010; Martins & McNeil, 2009; Morton et al., 2014). Motivational Interviewing can be delivered in brief, yet effective, doses particularly in situations where time is limited, such as in busy hospital clinics (Martins & McNeil, 2009; Rubak, Sandbæk, Lauritzen, &

Christensen, 2005; Vasilaki, Hosier, & Cox, 2006). Motivational Interviewing promotes a facilitative counselling environment and the level of MI acceptability amongst patients is high (Britt, Hudson, & Blampied, 2004; Martins & McNeil, 2009).

The following section provides a description of MI, then a detailed review of literature on MI in diabetes interventions.

### **What is Motivational Interviewing?**

Motivational Interviewing is an evidence-based behaviour change approach – it is defined as:

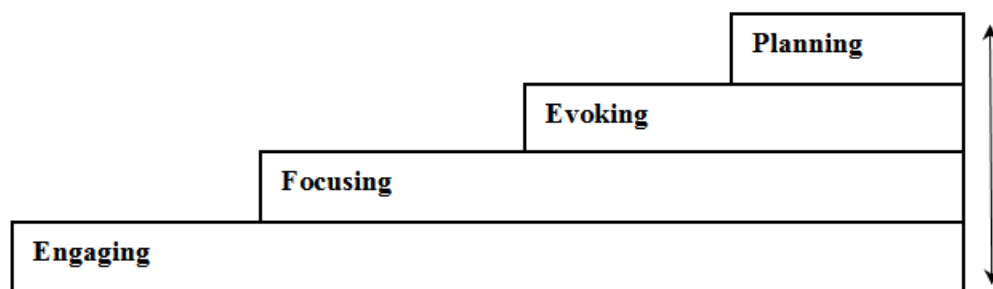
“a collaborative goal oriented style of communication with particular attention to the language of change. It is designed to strengthen the individual’s motivation for and movement towards a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion.” (Miller & Rollnick, 2013, p. 29)

Fundamental concepts of MI include an emphatic guiding communication style, working in a collaborative relationship towards achieving a mutually agreed change. This way of working is captured by what is termed the *Spirit of MI*, which comprises four elements: partnership, acceptance, compassion and evocation (Miller & Rollnick, 2013).

*Partnership* fosters the active role of the client in moving towards change and eliminates the authoritative role of a practitioner. The practitioner and client collaboratively work with each other, strengthening the client’s motivation for

change using the client's own resources for change. *Acceptance* refers to the right of a client to make decisions related to change; that is, if they want to change and how to make that change. This component honours the person's autonomy and recognises their absolute worthiness in making decisions related to change. *Compassion* is to pursue the welfare and best interests of clients and to seek to understand clients' experiences, values, and motivations. This includes respecting others and their experiences and feelings without being judgmental. *Evocation* involves drawing out the client's own reasons and motivations for wanting to change through the practitioner guiding the conversation in order to elicit change talk, without imposing any ideas or motives on the client.

In addition, MI comprises four processes (Figure 4.1): engaging, focusing, evoking, and planning. These can be recursive, overlapping, and not necessarily applied in order (Miller & Rollnick, 2013).



**Figure 4.1.** The four processes in MI: engaging, focusing, evoking, and planning (Miller & Rollnick, 2013).

*Engaging* is the process of establishing a working relationship between both the client and practitioner. A working alliance needs to be sustained throughout the



consultation to facilitate positive outcomes (Miller & Rollnick, 2013). *Focusing* involves mutually establishing a particular agenda or area of potential change and maintaining a focus of conversation in the direction of the desired change. *Evoking* is to facilitate, from within the client's conversation, the emergence of motivations for change or movement in the direction of change. That is, the practitioner skilfully guides the conversation to elicit and strengthen the clients talk about change. *Planning* is to develop a specific action plan that would promote positive changes for the client using the client's own resources when the client reaches a stage of being ready and committed to change.

Motivational Interviewing also involves using micro-counselling skills of reflections, open-ended questions, affirmations, and summaries. These micro-counselling skills are used throughout the four processes (Miller & Rollnick, 2013).

*Reflective listening* is a core skill in MI and good MI practice involves the practitioner using more reflections than questions (Miller & Rollnick, 2013). Reflections take two main forms: simple or complex. *Simple reflections* are to repeat or rephrase what the client said to clarify or emphasise understanding of the client's part of the conversation. In contrast, *complex reflections* add new meanings based on what the client said, and are more powerful than simple reflections. As an example, reframing or paraphrasing specific parts of the conversations can help evoke the client's motivations for change and to make clients recognise the deeper meaning of what they spoke out.

*Open-ended questions* are useful to elicit elaborative answers that may guide change, compared to closed questions that have yes-no or factual answers. The latter

limits the conversation while the former, especially evocative questions, expands it to facilitate the MI processes. *Affirmations* are reinforcement statements to acknowledge the client's positive actions, efforts or strengths with the view to strengthening the client's self-efficacy and confidence in their ability to change. *Summaries* are useful both to bring together the shared understanding from the collaborative conversation between the client and practitioner, and also to highlight specific parts of the conversation that may facilitate change. Summaries may also be used to maintain focus or to shift focus if necessary.

Eliciting and strengthening change talk is a key component of MI. *Change talk* is "any self-expressed language that is an argument for change" (Miller & Rollnick, 2013, p. 159). Change talk was found to be related to positive client outcomes (Apodaca & Longabaugh, 2009; Magill et al., 2014). Examples of change talk are: desire to change (e.g., want and wish), ability to change (e.g., can and able), reasons to change (e.g., if, then statements), needs to change (e.g., must and have to), commitment (e.g., promise), activation (e.g., willing), and taking steps. Opposite to change talk is *sustain talk* which is the client's speech not in favour of moving towards change, or sustaining the current behaviour (e.g., I don't want to test my blood glucose and adjust the insulin dose).

A skilled MI practitioner will manage sustain talk during the session so that it is quietened and avoid the emergence of discord. *Discord* is when the client becomes defensive, arguing, talking over the practitioner, is inattentive, or displays behaviours that signal dissonance in the practitioner-client relationship. The practitioner, metaphorically speaking, needs to maintain a dancing partnership rather than a wrestling encounter with the client. Sustain talk and discord are predictive of non-

change and their emergence is related to the practitioner's behaviour (Miller & Rollnick, 2002; Moyers & Martin, 2006).

Motivational Interviewing can be learnt and applied by individuals from a wide range of backgrounds and expertise, such as health practitioners, counsellors, and researchers (Miller & Rollnick, 2013). It can be learnt through attending workshops, role plays, systematic feedback, supervision, and ongoing peer support (Miller & Rollnick, 2013). Training, ongoing coaching, and feedback ensure effective implementation of MI and optimises outcomes, which would otherwise be compromised by poor delivery of MI (Miller & Rollnick, 2013). Research shows that a practitioner's in-session behaviours have an influence on client language and can predict clients' outcomes (Apodaca & Longabaugh, 2009; Magill et al., 2014; Moyers & Martin, 2006). Poor delivery may include engaging in MI-inconsistent behaviours (confronting, directing, and warning) and there is evidence that high levels of MI-inconsistent behaviours are predictive of poor client's outcomes (Apodaca & Longabaugh, 2009).

Evaluation of MI treatment fidelity is essential to provide feedback for training and clinical supervision, and for clinical trials of MI (Jelsma, Mertens, Forsberg, & Forsberg, 2015; Miller & Rollnick, 2013). Treatment fidelity can be used to evaluate whether a treatment has been implemented effectively (i.e., treatment integrity), and to differentiate treatments in clinical trials (i.e., treatment differentiations). The use of reliable and empirically validated tools are necessary for measuring treatment fidelity and are becoming a pre-condition to interpreting results in clinical trials of MI (Christie & Channon, 2014; Jelsma et al., 2015). Formal and reliable assessment measures include Motivational Interviewing Treatment Integrity

(MITI) Code 3.1.1 (Moyers, Martin, Manuel, Miller, & Ernst, 2010) and its recent revision, the MITI 4.0 (Moyers, Manuel, & Ernst, 2014).

Research is still emerging evaluating the efficacy of MI for health behaviour change, such as diabetes self-management. The following provides a review of literature evaluating the efficacy of MI in diabetes interventions.

### **Motivational Interviewing in Diabetes Interventions**

Motivational interviewing has been investigated in the context of diabetes research including type 1 and type 2 diabetes and across different age ranges. The interventions have included MI as a standalone intervention, in addition to other intervention components, or an adapted form of MI-based interventions – in this thesis, these forms will be collectively referred to as MI interventions unless otherwise stated.

Motivational Interviewing has shown promise in improving diabetes outcomes, such as those related to diabetes management and psychosocial functioning (Christie & Channon, 2014; Hettema, Steele, & Miller, 2005; Martins & McNeil, 2009). The evidence, however, is still not conclusive. Uncertainty has arisen from weak study designs (with threats to internal and external validity) and lack of adequate fidelity measures which leads to a lack of clarity regarding the treatment integrity and interventionists competence in delivering MI (Christie & Channon, 2014; Mulimba & Byron-Daniel, 2014).

A meta-analysis and systematic review by Jones et al. (2014) examined the effect of MI on HbA1c in people with type 1 and type 2 diabetes. The review

identified 13 randomised controlled trials (RCTs) that measured changes in HbA1c before and after treatment. The majority of these studies included adults with type 2 diabetes; only three studies recruited children and adolescents with type 1 diabetes. A total of six studies found significant reduction in HbA1c in the MI group post intervention (Brug et al., 2007; Chen, Creedy, Lin, & Wollin, 2012; Hawkins, 2010; Rubak, Sandbaek, Lauritzen, Borch-Johnsen, & Christensen, 2011; Welch, Zagarins, Feinberg, & Garb, 2011; West, DiLillo, Bursac, Gore, & Greene, 2007). Two of these studies also found significantly lower HbA1c compared to that in the control group (Channon et al., 2007; Hawkins, 2010); and one study found that both intervention and control groups had lower HbA1c but the controls had the lower mean HbA1c (Welch et al., 2011). In contrast, four studies did not find any significant changes in HbA1c post intervention (Ismail et al., 2010; Minet, Wagner, Lønvig, Hjelmberg, & Henriksen, 2011; Pill, Stott, Rollnick, & Rees, 1998; Robling et al., 2012), and eight studies did not find any significant difference in changes in HbA1c between the MI and control groups (Brug et al., 2007; Chen et al., 2012; Ismail et al., 2010; Minet et al., 2011; Pill et al., 1998; Robling et al., 2012; Rubak et al., 2011; West et al., 2007).

In contrast to the above findings, one study found a significant increase in HbA1c in both the MI and control groups; but with a significantly higher increase in the control group than in the MI group (Partapsingh, Maharaj, & Rawlins, 2011). Furthermore, in a study that used MI-based education sessions, HbA1c increased significantly post intervention, and was significantly higher compared to the control group (Wang et al., 2010).

The meta-analysis and systematic review by Jones et al. (2014) found that

HbA1c decreased by 0.17% (95% CI: -0.09, 0.43%) post MI interventions, compared to control groups. This decrease, however, was not statistically significant. Jones et al. (2014) concluded that the impact of MI interventions on metabolic control appears to be inconclusive, based on their review of the small number of studies available and the limitations in the research, such as those mentioned previously.

A review by Christie and Channon (2014) found that MI was generally effective in improving diabetes outcomes in the paediatric and adult populations. Findings from the studies on adults provided evidence for improvements in HbA1c, self-management, self-efficacy, diabetes knowledge and QoL in individuals who received an MI intervention compared to control groups (Christie & Channon, 2014). Nonetheless, MI did not have an impact on diabetes management in all of the studies, with positive effects not detected in two of the adults studies (Christie & Channon, 2014).

In the paediatric and youth population, Christie and Channon (2014) reported six studies of children and adolescents with type 1 diabetes. These studies had findings that mostly suggest the potential effectiveness of MI for young people with diabetes (Christie & Channon, 2014). Christie and Channon (2014), however, also reported that the current studies suffer methodological weaknesses, such as lacking fidelity checks of the quality of the MI delivered. They state that “it is essential that studies carefully address the process and fidelity issues as a precondition for seriously evaluating outcomes of Motivational Interviewing interventions in order to create a clearer picture of its role in facilitating change in health behaviour” (Christie & Channon, 2014, p. 385).

A recent meta-analysis by Gayes and Steele (2014) concluded that MI is an effective and appropriate intervention for targeting health behaviour changes in young people, with MI having a positive impact on both physical and psychosocial health outcomes where the target was several health conditions. They found that MI had the largest effect size (Hedges's  $g = 0.914$ ) for type 1 diabetes, of all the other health conditions (paediatric obesity, dental health, calcium intake, and asthma) examined in the meta-analysis. It should be noted, however, that these conclusions were based on only four studies that included MI in an intervention for young people with type 1 diabetes (Channon et al., 2007; Channon, Smith, & Gregory, 2003; Viner, Christie, Taylor, & Hey, 2003; Wang et al., 2010). Three of these studies evaluated the effect of a combined intervention that included an MI component and had inconsistent results. In addition, fidelity data were not provided.

The following sections present a detailed review of studies that included MI in interventions that target youth with type 1 diabetes. Studies that used MI as a standalone intervention are detailed first, followed by research that used MI-based or that used MI as an adjunct component in interventions for youth with type 1 diabetes.

### **Standalone MI interventions with youth**

In a pilot UK study by Channon et al. (2003) the impact of MI on metabolic control, diabetes self-management, and well-being was investigated. The study included 22 adolescents (14-18 years old) with poorly controlled type 1 diabetes. The mean HbA1c for the MI group was 10.8%, and 10.1% for the control group. The control group ( $n = 25$ ) consisted of those who declined to participate in the intervention but had their HbA1c available for the study. The MI intervention period

was 6 months, unless a participant selected not to continue. Participants in the MI group had the choice of determining the number of sessions within the intervention period. The sessions were conducted by the same interventionist each time. The mean number of sessions over the intervention period was five sessions (min = 1 session; max = 9 session, with a mean of 4.7). The intervention was delivered by a researcher trained in MI. The training was conducted over 3 months, and consisted of a workshop, training videos, role play and supervision. Weekly supervision took place during the intervention using recorded sessions. Treatment fidelity was not reported and it is not clear whether this was evaluated using formal measures or was based on observational feedback from the supervisor.

Outcome measures included HbA1c and psychosocial questionnaires. The HbA1c data were measured three times within 6 months (i.e., baseline, during, and post the intervention). The psychosocial questionnaires (pre-intervention and post-intervention,) included: Well-being Questionnaire (WQ), Diabetes Knowledge Scale (DKS), Summary of Diabetes Self-care Activities (SDSCA), the Diabetes Readiness to Change Questionnaire (RCQ), and Personal Models of Diabetes Questionnaire (PMDQ), which measures illness perceptions. Participants also filled out Post-Intervention Satisfaction Questionnaire (PISQ).

There was a significant reduction in HbA1c both during and post the intervention compared to the mean HbA1c at baseline; the reductions were 1.1% and 0.8%, respectively. Conversely, there was no significant reduction in HbA1c in the control group. The majority of the psychosocial questionnaires did not have significant changes. There were, however, significant changes in two dimensions of the PMDQ: there was a significant reduction in fear of hypoglycaemia, and also



improved perception for coping with diabetes. The PISQ indicated that youth made at least one positive diabetes self-management behaviour change. The DRCQ also had some changes for 39% of the participants, of which the majority (64%) indicated a movement towards action, and a minority (27%) indicated a decrease in readiness to change. These results need to be treated with caution because of the small number of participants.

This pilot study by Channon et al. (2003) provided evidence for the potential efficacy of MI as an intervention for youth with poorly controlled type 1 diabetes. The study however had limitations. Channon et al. (2003), on the one hand, found that youth reported at least one behavioural change in the PISQ. On the other hand, significant changes were not found in the scores of SDSCA. This inconsistency, according to the authors, made the results (including significant changes in HbA1c) difficult to interpret but the reported inconsistency could well be because of the lack of statistical power required to detect significant changes on the SDSCA. The small sample size and homogenous sample also limited the generalisability of the results. Moreover, during the intervention half of the HbA1c data were missing ( $n = 11$ ), and post-intervention only 17 participants had a record of HbA1c. For these reasons, the results need to be interpreted cautiously (Channon et al., 2003). It was also unclear if the observed changes could be attributed to the MI rather than to other factors (e.g., placebo effect of regular contact with the researcher or simply the passage of time). Consequently, as a result of the difficulties in interpreting the study data, Channon et al. (2003) suggested that future research includes more intensive assessment of change and behavioural markers of diabetes self-management behaviours.

Huws-Thomas (2007) recruited 66 teenagers with type 1 diabetes from five

diabetes clinics in South Wales, UK. The inclusion criteria were adolescents aged 14-17 years old who attended participating diabetes centres. A cut-off HbA1c value was not determined; hence the study was open to adolescents with both good and poor diabetes control. Teenagers were excluded from participation if they were newly diagnosed with type 1 diabetes, had learning disabilities and disorders of communication, or had other conditions that could interfere with an investigation of intervention effects (e.g., thyroid dysfunction).

The study participants were randomly assigned to an MI intervention group, or to a control group, who received support visits. Participants in each group received individual sessions within a period of 12 months. The frequency and location of appointments in the MI group was less structured than that in the control group. The latter involved arranging appointments every 6-8 weeks (mean of 6 visits), whereas the former was determined by the participants (mean number of visits was 4).

The same practitioners implemented the intervention each time. The control group received support visits from two diabetes nurses. The MI intervention was delivered by the study principal investigator, who was in training as a health psychologist. She received MI training by two professional MI trainers. The training took place prior to the intervention, with supervision and feedback during the intervention. The training and feedback were mostly based on observations from simulated and actual in-session behaviours. A formal method of evaluation was not used, and Huws-Thomas (2007) stated:

“Due to time constraints it was decided not to use formal MI assessment tools such as Motivational Interviewing Skill Code [(MISC)

Miller, 2000]. The most preferred method of learning was based on the role of SC as an ‘expert coach’ with specific structured feedback based on positive reinforcement and collaborative problem solving. This structured feedback took the form of a) written observations and suggestions for improvement and b) face to face feedback during supervision.” (p. 140)

The primary outcome measure was HbA1c, and a battery of psychosocial questionnaires constituted the secondary outcome measures. The psychosocial assessments included using: PMDQ, Self-Efficacy for Diabetes Scale (SED), DQoL Measure for Youths, and WQ. All of the questionnaires were completed at baseline and 12 months; DQoL and WQ were also completed at a 24-month follow-up. The HbA1c was assessed at baseline, 6-month, 12-month, and 24-month post intervention. The baseline HbA1c mean of the MI and control groups were, respectively, 9.3% ( $SD = 2.1\%$ ) and 9% ( $SD = 1.56\%$ ).

There were significant differences in results for the primary and secondary outcome measures between the study groups, after adjusting for baseline values. The difference in mean HbA1c between the study groups was statistically significant at the 12-month follow-up (difference = 0.5%,  $p = 0.04$ ), and a similar result was maintained at the 24-month follow-up (difference = 0.4%,  $p = 0.003$ ). The MI intervention group had significantly lower HbA1c than the control group, suggesting improved metabolic control in the MI group at both follow-up. The analysis was based on the complete dataset from 47 participants (MI group  $n = 27$ , and control group  $n = 20$ ).

At the 12-month follow-up, DQoL, well-being, and illness perceptions were

also significantly different between the study groups ( $p < 0.005$ ). The MI group, compared to the control group, had greater life satisfaction, lower level of worry, experienced less anxiety, had more positive well-being, and perceived diabetes to have a lesser impact on their lives. The MI group also had higher scores on the total PMDQ, compared to that in the control group, suggesting the MI group had less threatening views on diabetes. Scores on the self-efficacy questionnaire, although indicated a higher level of confidence in the MI group compared to that in the control group, were not statistically significantly different.

Statistical differences in scores of some of the scales between the study groups were maintained at the 24-month follow-up, but with a smaller difference from that found at the 12-month follow-up. The MI group, compared to the control group, had greater satisfaction, lower level of worry and anxiety, and diabetes had a smaller impact on their lives at 24-month follow-up.

This study provides evidence for the efficacy of a standalone MI intervention with adolescents who have type 1 diabetes, with improvement in both HbA1c and psychosocial outcomes. The multi-centre study design increases the generalisability of the results; however, there were limitations to the study. More than half of the study participants (i.e., 52% of total participants,  $n = 34$ ; and 58% of the MI participants,  $n = 22$ ) had good metabolic control ( $\text{HbA1c} < 8\%$ ,  $M_{[n=34]} = 7.2\%$ ), and therefore do not represent those youth with type 1 diabetes with poor diabetes control who are most in need of intervention. In addition, Huws-Thomas (2007) did not include measures to assess different self-management behaviours, such as SMOBG. Assessing adherence to diabetes self-management behaviours is a standard clinical practice/check for type 1 diabetes and there has been a strong recommendation to

include such data in clinical trials (Hampson et al., 2001; Jones et al., 2014).

Finally, formal evaluation methods to assess the MI fidelity were not used in the Huws-Thomas (2007) study. Huws-Thomas (2007) stated that internal validity and skill efficacy in MI were sufficiently observed by an on-going process of supervision and feedback. In addition, discriminant validity could not be determined because there were technical difficulties with the number and quality of the recorded audios and therefore, it was not formally assessed whether the treatment in the MI intervention group compared to the supportive counselling group were distinctive from each other. Furthermore, Huws-Thomas (2007) stated that the simultaneous occurrence of the interventionist training, intervention development, and supervision in a short time span was one of the key weaknesses in the study. This also suggests that the MI would have been applied more skilfully towards the end of the intervention and may have created a bias in results.

### **Multicomponent interventions which include MI**

A qualitative preliminary study evaluated the impact of an intervention that comprised of MI and externalising conversations (EC) in adolescents with type 1 diabetes (Knight et al., 2003). Twenty adolescents with type 1 diabetes were recruited from child and adolescent diabetes services in the UK. The participants were adolescents (aged 13-16 years) with type 1 diabetes who had difficulties adjusting to or coping with diabetes. Eligible adolescents, who were willing to engage in the intervention procedure, constituted the intervention group ( $n = 6$ ) and the remaining eligible participants preferred to be part of the control group ( $n = 14$ ), standard care.

The intervention comprised of six 1-hour weekly group sessions, which were based on MI and EC. The intervention was delivered by a senior registrar in child psychiatry and also by a community psychiatric nurse. The study did not report on the interventionists' training in MI, and there was also no data on treatment fidelity.

The study groups completed questionnaires that included components on illness perceptions, emotional reactions, and coping mechanisms towards diabetes. The questionnaires were completed pre-intervention and post-intervention, and at the 6-month follow-up. The results suggest that the MI-EC intervention was successful in improving diabetes illness perceptions in adolescents. The intervention group, compared to the control group, demonstrated less threatening views on diabetes, had more sense of perceived control, more acceptance of their condition, and had lower perceived impact of diabetes on their lives.

Viner et al. (2003) evaluated a motivational and solution-focused therapy group intervention to improve glycaemic control in young people, aged 11-17 years. The study recruited 41 adolescents with poorly controlled type 1 diabetes ( $HbA1c > 8.5\%$ ) from four urban UK hospital diabetes clinics. Six weekly group sessions were offered in the intervention, in groups of four to five young people per session. The control group consisted of adolescents who were invited to participate but who opted not to participate and they received standard care.

The intervention was based on several approaches and had a combination of techniques adopted from the following four approaches: MI, solution-focused therapy, cognitive behaviour therapy (CBT), and systemic and narrative therapy. The motivational enhancement component in the study was based on using MI and

included: addressing ambivalence (e.g., discussing the advantages and disadvantages of change), enhancing motivation to change (e.g., reflection of motivational statements), and preparation to change (e.g., psycho-education). Training of the interventionists (and their expertise, educational, or clinical background) was not described, and there was also no data on treatment fidelity.

The outcome measures included an assessment of glycaemic control (HbA1c) and psychosocial questionnaires: the Strengths and Difficulties Questionnaire (SDQ); and the SED scale. The psychological assessments were collected at baseline and repeated 6 months post intervention. Glycaemic control was assessed at baseline and then three time points grouped as 1-3 months, 4-6 months and 7-12 months. A combined intervention effect was assessed without individually assessing which intervention component was the most or least effective. The mean HbA1c in the intervention and control groups were 10.2% and 10%, respectively, at baseline. At the 4-6 month follow-up, HbA1c dropped to 8.7% and 9.8%, respectively. There was a significant improvement in HbA1c at 4-6 months post-intervention (i.e., 1.5% reduction in HbA1c) compared to no significant change in the control group. This improvement was partly maintained at 7-12 months post-intervention from baseline (i.e., 1.3% reduction in HbA1c), but there was no significant difference between the intervention and control groups. There was also a significant improvement in self-efficacy in the intervention group at the 6-month follow-up (mean SED Pre, 145, SED Post = 158;  $F = 6.7$ ,  $p = 0.014$ ), but not in the control group.

Nansel et al. (2007) evaluated the effect of a diabetes self-management intervention, or what they referred to as a *diabetes personal trainer* intervention, for youth with type 1 diabetes. The study recruited 81 adolescents (aged 11-16 years old)

with type 1 diabetes from two paediatric endocrinology clinics in Baltimore, Maryland, USA. Participants were eligible to take part in the study if they had diabetes for at least one year; there was no inclusion criteria based on HbA1c of a specific level (i.e., participants with good or poor diabetes control were eligible to participate).

The intervention was guided by principles of MI, applied behaviour analysis, and problem-solving. The use of MI in the intervention was mainly to engage participants in the intervention and to facilitate the use of applied behaviour analysis. MI was also used to facilitate collaboration between the trainer and adolescents, and to avoid the participants perceiving the trainer as another authority figure that dictates orders with regard to diabetes management.

The intervention consisted of six sessions and supplementary telephone calls conducted over a period of 2 months. The initial intervention session was conducted with both the adolescent and a parent and subsequent sessions involved the adolescent only. The non-professional interventionists (i.e., personal trainers) received 80 hours training in several areas related to the intervention, including diabetes management, MI, applied behaviour analysis, and parent-child issues in diabetes management. The training procedures included educational sessions, role plays, group activities, and individual practice with feedback. There were also weekly group supervisory sessions for the personal trainers. The authors report that the fidelity of MI was monitored to ensure adequate competency in delivering MI – a sample of recorded intervention sessions were evaluated for all trainers and were found adequate – but the authors did not provide data to support this.



The outcome measures comprised: metabolic control (measured by HbA1c), adherence (measured by a Diabetes Self-Management Profile), and psychosocial factors (measured by DQoL, SEDM, OEDM-N, and OEDM-P). Data were collected at baseline and at 12-month follow-up (Nansel et al., 2007). Additional follow-up data included self-report data (adherence, self-efficacy, and outcome expectations) collected at 6-month, and HbA1c data assessed at 9 months. The latter was also obtained from medical records 24-month post intervention (Nansel et al., 2009).

At the 9-month and 12-month follow-up the results suggested that there was a trend for an overall intervention effect on HbA1c ( $F = 3.71, p = 0.06$ ;  $F = 3.79, p = 0.06$ , respectively), with a significant intervention-by-age interaction ( $F = 4.78, p = 0.03$ ). The significant interaction term suggested that the intervention had a greater effect on HbA1c in older adolescents than in younger ones. A further stratified analysis of the intervention effect on two age groups, 11-13 years ( $n = 42$ ) and 14-16 years ( $n = 36$ ), revealed that the intervention significantly reduced HbA1c ( $p = 0.02$ ) only in the older age group. Similar results were obtained at the 24-month follow up, with slight improvements. There was a reduction in the HbA1c, from baseline, in the intervention group (0.39%), whereas there was an increase in the control group (0.3%). There was a significant overall effect of the interaction on HbA1c ( $F = 6.92, p = 0.01$ ) and a significant intervention-by-age interaction ( $F = 7.71, p = 0.01$ ) (Nansel et al., 2009). Analysis of the psychosocial measures showed no intervention effect, with the exception of 12-month follow-up when the intervention group had lower positive outcome expectations and reported higher disease impact, compared to the control group.

Wang et al. (2010) compared MI-based education and structured diabetes

education (SDE) for improving metabolic control and psychosocial outcomes in adolescents with type 1 diabetes. The study recruited children and adolescents aged 12-18 years, with poorly controlled diabetes ( $\text{HbA1c} \geq 9\%$ ), from the Children's Medical Centre in Dallas, USA. The participants were randomised to either MI-based education ( $n = 21$ ) or SDE ( $n = 23$ ).

Two MI-based education sessions were provided: one immediately after baseline and the other 3-4 months later. In addition, participants received two telephone follow-ups scheduled one and two months after baseline. A third education session was also provided for participants who continued to have poor diabetes control ( $\text{HbA1c} \geq 9\%$ ). The MI-based education used MI at the beginning of the intervention, followed by one or more educational sessions. There was no information on the frequency of sessions in the SDE group.

Three diabetes educators delivered the MI-based intervention, and six educators were assigned to the SDE group. The latter group did not receive additional training. The MI interventionists received training from an MI trainer and psychologist in the form of a 2-day workshop, but the trainer's level of skill in MI was not noted. The authors stated that "skill refreshers were done with an MI psychologist" (Wang et al., 2010, p. 1741), but there was no information on feedback or on-going supervision. All of the MI and SDE visits were recorded and coded by a blinded coder, who also received a 2-day workshop training in MITI 3.0.

The HbA1c and psychosocial data were collected at baseline, 3-month, 6-month, and 9-month follow-up points (T0, T1, T2, and T3, respectively). The psychosocial questionnaires included: Centre for Epidemiologic Studies Depression

Scale (CES-D), the Epidemiology of Diabetes Interventions and Complications Quality of Life Questionnaire (EDIC-QOL), and the SDSCA.

The SDE group had significantly lower HbA1c than the MI group over the 6-month follow-up and after adjusting for T0 ( $F = 4.84$ ,  $p = 0.03$ ). There were no significant differences in the psychosocial scores between the two groups at any of the follow-up points and after controlling for baseline measurements. The MITI coding results showed that the spirit was 4 on average (at the competent level). The percent of MI-adherent, however, was 70% which is below beginning proficiency (i.e., <90%). In addition, other MITI summary scores (e.g., %reflection-to-question ratio) were not reported. This suggests that although those who provided the MI-based education may have generally been consistent with the spirit of MI, they did engage in behaviours inconsistent with MI, and their skill level was unclear for other key MI practitioner behaviours.

Robling et al. (2012) evaluated *Talking Diabetes*, a consulting skills intervention aimed to train health practitioners to guide sessions constructively with a focus on agenda settings and support of patient led behaviour change. The study by Robling et al. (2012) is referred to as the DEPICTED study: the Development and Evaluation of a Psychosocial Intervention in Children and Teenagers Experiencing Diabetes. The study design was a pragmatic cluster RCT, which involved 26 participating UK diabetes services. Seventy-nine healthcare practitioners (13 teams) received training in the intervention, and 359 children with type 1 diabetes aged 4-15 years and their main carers were in the intervention group; the control group had 13 teams, and 334 children with type 1 diabetes and their main carers.

*Talking Diabetes* used an approach that aimed to equip practitioners with skills for constructive sessions that facilitate and enhance adolescents' engagement in their own health care and diabetes management. The intervention used a guiding communication style, shared agenda setting, person-centred approach, and had discrete strategies and skills drawn from MI. Information on the discrete strategies and skills drawn from MI were not clearly described.

The training of practitioners included using web-based modules (e.g., formal didactic content) and two training workshops two weeks apart were delivered by two trainers. The workshops provided review, practice, and feedback on strategies and skills of the intervention. Training specific to MI skills was not clearly described in the paper. The authors used a supplemented version of an earlier version of a MITI measure by Moyers, Martin, Manuel, Hendrickson, & Miller (2005) to suit the combined intervention. For elements that were relevant to MI the study reported on treatment fidelity data on scales of guiding style and spirit (evocation, collaboration, and autonomy-support). The scores on the spirit ratings were below the standard MI beginning proficiency (i.e.,  $< 3.5$ ) before and after training. The study did not report on other practitioner behaviours such as the percentage of complex reflections or open questions.

The primary outcome measure was HbA1c, which was collected at baseline and at 12-month follow-up. The mean HbA1c at baseline for the control group was 9.2% ( $SD = 1.8\%$ ) and for the intervention group was 9.4% ( $SD = 1.8\%$ ). Secondary outcome measures included: clinical measures (hypoglycaemic episodes, body mass index, and insulin regimen); and psychosocial questionnaires, including general and diabetes-specific QoL, emotional adjustment to diabetes, self-reported and carer-

reported importance of, and confidence in, undertaking diabetes self-management. The level of HbA1c slightly increased in both groups from baseline to follow-up (intervention group = 9.7%; and control groups = 9.5%), but there was no significant difference between the intervention and control groups. The intervention had no effect on the secondary measures except for a few changes. An increase in the short-term ability to cope with diabetes in the intervention group was observed and carers in the intervention group reported greater excitement about clinic visits and improved continuity of care. In contrast, some aspects of diabetes-specific QoL improved in the control group, compared to the intervention group, manifested by reduced problems with treatment barriers and with treatment adherence. The overall results of this study suggested that there was no improvement in diabetes outcome as a result of the intervention. The intervention, however, was not entirely MI and the level of skills of the practitioners was below beginning proficiency on the fidelity measure.

A pilot study by Stanger et al. (2013) adapted a multicomponent motivational intervention, which included MI/CBT and family-based contingency management (CM) for adolescents with poorly controlled type 1 diabetes. The study recruited 17 adolescents (ages 12-17 years) with poorly controlled type diabetes, and their parents, from the Arkansas Children's Hospital Endocrinology Clinic, USA. The mean pre-treatment HbA1c was 11.6% ( $SD = 2.5\%$ ), and the mean SMOBG frequency per day was 4.1 ( $SD = 1.9$ ).

Adolescents and their parents received 1-hour-per-week sessions over 14 weeks of MI/CBT, clinic-based CM, and parent-directed CM. The intervention sessions were delivered by Masters' level clinicians, who had weekly supervision sessions with the study principal investigator (supervisor). The interventionists had to

complete structured adherence checklists after each session, which were reviewed by the supervisor to ensure completion of treatment components. The MI section of the intervention included a menu, which was adopted from a study by Channon, Huws-Thomas, Gregory, and Rollnick (2005). Training and treatment fidelity specific to MI were not reported. The outcome measures were HbA1c, SMOBG frequency (was downloaded weekly during the 14 weeks of treatment), and an assessment of adherence measured by the Self-Care Inventory (SCI).

All outcome measures had significant improvement from pre-intervention to post-intervention. The HbA1c improved by 2.5% ( $p < 0.0001$ ), the SMOBG frequency increased by 2.2 tests per day ( $p < 0.001$ ), and there was an increase in the SCI score indicating improved level of adherence. These results, therefore, support the potential efficacy of a multicomponent motivational intervention for youth with poorly controlled type 1 diabetes.

A multicentre RCT was conducted to investigate the effect of MI and CBT on metabolic control in adolescents with type 1 diabetes (Berger et al., 2013; Rami-Merhar et al., 2014). The study applied MET, which is MI including giving feedback to participants, such as HbA1c information. Participants in the study ( $n = 75$ ) were Austrian children and youth (aged 13-20 years) with poorly controlled diabetes. The participants were randomised to an intervention group receiving individual MI and CBT sessions and control group receiving standard treatment, over a period of 6 months. The intervention group had four sessions of MI, eight sessions of CBT, and 10 supportive e-mail correspondences conducted by trained clinical psychologists. Information on the interventionists training and data on treatment fidelity were not

available in the abstract and a publication of a full manuscript was not available at the time of writing this thesis. Glycaemic control was assessed at baseline and then at the 6-month, 12-month, and 24-month follow-up. The baseline HbA1c for the intervention and control groups was: 9.95% ( $SD = 0.26\%$ ) and 9.24% ( $SD = 0.28\%$ ), respectively.

There was a slight improvement in HbA1c in the intervention group (9.74%;  $SD = 1.75\%$ ), but this was not statistically significant at the 6-month, 12-month, and 24-month follow-up. Analysis of stratified age groups revealed that older youth (aged 16-20 years old) in the intervention group had significantly improved HbA1c compared to the younger group, ( $p = 0.032$ ). This suggests that youth, compared to children, may have benefited more from the combined MI and CBT intervention. Gender differences were apparent at the 6-month follow-up, with males in the intervention group having improved HbA1c compared to females (who had a slight increase in HbA1c). The control group, in contrast, did not have significant differences based on gender. Thus, although the overall results did not indicate the effectiveness of the intervention, it appears that this intervention may be more effective for older youth. The above study showed the potential benefit of a combined MI and CBT intervention.

Christie et al. (2014) examined the efficacy of the Child and Adolescent Structured Competencies Approach to Diabetes Education (CASCADE), which provided an intensive psycho-educational structured programme that incorporates motivational, patient-centred, and psychological approaches to improve metabolic control and psychosocial functioning in young people with type 1 diabetes. The study involved multiple UK centres and many healthcare practitioners; 28 paediatric

diabetes services across London, south-east England and the Midlands, and 43 health professionals, grouped in 14 teams, were trained in the intervention. The study recruited 362 children and adolescents (aged 8-16 years) with poorly controlled type 1 diabetes (i.e., HbA1c  $\geq$  8.5%). The mean HbA1c of the intervention and control groups were 9.9 mmol/L (*SD* = 1.5 mmol/L) and 10 mmol/L (*SD* = 1.5 mmol/L), respectively.

The intervention comprised four group education sessions delivered by a paediatric diabetes specialist nurse and another team member (healthcare practitioner). The interventionists received structured training workshops that were conducted over two days, followed by a one-day refresher training, and ongoing support during the intervention (e.g., queries-related or supportive telephone calls). Information specific to the trainers' skills in MI was not reported. The workshops included training in multiple components that were related to the intervention content, the underpinning philosophy and delivery skills. The intervention was described as being based on MI and solution-focused therapy. Components drawn from MI were integrated in the intervention and included: open-ended questions, affirmations, reflective listening, simple summaries, considering the pros and cons of behaviour change, and establishing the importance and confidence of change. In addition, an active rather than passive approach in the role of patients in their diabetes management was integrated in the intervention. The fidelity of the overall delivery of the intervention was measured in this study, but treatment fidelity measures specific to MI were not available.

The primary outcome was glycaemic control, measured by HbA1c at baseline



and follow-up (i.e., 12 months and 24 months post intervention). The secondary outcomes measures included psychosocial questionnaires and surveys that were related to diabetes self-management. These measures included: general and diabetes-specific QoL (PedsQL modules); emotional and behavioural adjustment (SDQ); diabetes self-efficacy scale (DSES); decision-making, skills and responsibility for diabetes management (The Diabetes Family Responsibility Questionnaire, DFRQ); diabetes regimen, including insulin dose and number of injections; frequency and severity of hypoglycaemic episodes; and frequency of hospital admissions and the reason for admission. The questionnaire data were collected at baseline and at follow-ups (12-month and 24-month).

There were no significant changes in the primary and the secondary outcome measures at the 12-month or 24-month follow-up, which suggests that the intervention had no impact on metabolic control or secondary outcomes. Further analysis revealed that higher level of HbA1c predicted an increase in HbA1c at 12 months, which suggested a poor response to the CASCADE intervention.

### **Summary**

There are currently ten studies in total that have included MI in interventions to improve diabetes outcomes for youth with type 1 diabetes. Only two of these studies investigated the effect of a standalone MI intervention (Channon et al., 2003; Huws-Thomas, 2007); the remaining eight studies incorporated MI as an adjunct intervention component or adapted some of the MI strategies and skills in the interventions (Christie et al., 2014; Knight et al., 2003; Nansel et al., 2007; Rami-Merhar et al., 2014; Robling et al., 2012; Stanger et al., 2013; Viner et al., 2003;

Wang et al., 2010).

The majority of studies had results that suggested positive intervention effects on diabetes outcomes, as evidenced by reductions in HbA1c, increased SMOBG, better QoL, and improved psychosocial functioning (Knight et al., 2003; Nansel et al., 2007; Rami-Merhar et al., 2014; Stanger et al., 2013; Viner et al., 2003). The study samples comprised mostly children and adolescents younger than 18, except for the study by and Rami-Merhar et al. (2014), which included individuals aged up to 20 years old. Rami-Merhar et al. (2014) found that older youth (aged 16-20 years old) in the intervention group had significantly improved HbA1c compared to the younger group (13-15 years old).

Two of the studies that implemented multicomponent interventions, reported no intervention effects (Christie et al., 2014; Robling et al., 2012). These two studies, as well as other studies that incorporated strategies and skills from MI in their multifaceted interventions, evaluated the effect of the interventions as a whole rather than the effect of MI on its own (Christie et al., 2014; Robling et al., 2012).

Finally, the one study that used an MI-based education intervention found that the control group (receiving SDE) had better outcomes compared to the MI-based education intervention group (Wang et al., 2010). Again, in this study, the effect of the combined intervention (MI + education) was analysed and the effect of MI on its own is unclear. Moreover, the level of MI skill was questionable in that study given that the interventionists engaged more MI non-adherent behaviour than recommended.

Although there appears to be emerging evidence of the potential of MI for

youth with type 1 diabetes, there are critical limitations in the above studies. These limitations make it difficult to draw conclusions specific to the efficacy of MI in diabetes interventions for youth. The weakness and limitations in the above reviewed research are presented in the following section.

### **Limitations of the research into MI and diabetes interventions for youth**

The findings of the current evidence for the efficacy of MI for youth are not based on specific evaluations of MI, with most interventions incorporating some form of MI, or elements of MI, and report analysis of the effect of combined approaches. For this reason the results are not explicit to MI, whether it is supporting evidence (positive intervention effects) or non-supporting evidence (having no or negative intervention effects). One conclusion to draw from the literature reviewed above is that determining the efficacy of MI in interventions for youth with diabetes is still in its infancy: there are only two MI-specific studies and the results of these are only tentatively promising.

Evidence from the two studies that evaluated MI in a standalone intervention also had limitations. Channon, Smith, and Gregory (2003) had difficulties interpreting their results, because of inconsistencies in their result data, and they also noted that the findings need to be considered with caution. They were unable to conclude if the observed changes were attributable to MI, or as the result of other factors, such as increased contact with youth. In addition, the small number of participants and missing data weakened statistical power.

A key weakness in Huws-Thomas (2007) was the study sample, which included 52% adolescents with good diabetes control (mean HbA1c = 7.2%), and

who, therefore probably had been doing relatively well in engaging in diabetes management behaviours. This study, therefore, did not address the common clinical challenge of engaging adolescents with poor diabetes control and to examine the efficacy of MI in influencing that. In addition, this study although it used the measures of HbA1c and a range of psychosocial questionnaires, it did not assess diabetes self-management behaviours, such as frequency of SMOBG. In examining the efficacy of MI, it is important to evaluate process variables related to behaviour change, this is in addition to primary variables such as blood glucose measures (Hunt, 2011; Jones et al., 2014). Changes in HbA1c come as a result of a complicated management process that involves lifestyle changes and adhering to, for example, SMOBG and adjusting insulin dose.

Neither Channon et al. (2003) nor Huws-Thomas (2007) formally evaluated the fidelity of the MI using reliable and validated coding systems. Evaluation of treatment fidelity is vital to ensure that what is perceived as MI in the intervention is actually MI and to assure the quality of the delivered MI (Jelsma et al., 2015). Miller and Rollnick (2013) state that “it is insufficient simply to claim that MI was provided in a clinical study. Outcomes are difficult to interpret apart from information about MI fidelity, for which a range of measures have already been developed and evaluated” (p. 380).

Evaluations of MI treatment fidelity, using validated MI fidelity measures (e.g., MITI), were also absent from the vast majority of studies, and incomplete in Wang et al. (2010). Wang et al. (2010) did report outcomes from a formally validated evaluation measure, MITI 3.0, yet they did not include data on essential evaluation components (e.g., % reflection-to-question ratio). The available data on the integrity

evaluation in Wang et al. (2010) suggested a low level of MI competency of the interventionists in delivering MI, specifically in being on average below beginning proficiency in adhering to MI. This is an example of why it is important to use quality assurance measures, so that results can be interpreted on the basis of a complete picture, rather than jumping into qualifying or disqualifying MI from being an efficacious intervention when important data is missing.

Research shows that interventionists' skills on MI fidelity measures is directly associated with client outcomes (Miller & Rollnick, 2013). This suggests that potential confounders relating to the proficiency skills in MI can be ruled out if adequate delivery of MI is ensured. In other words, if the fidelity measures reflect poor MI practice, then outcomes cannot be fully attributable to MI. Assessments of fidelity should be a precondition to clinical trials that evaluate the efficacy of MI (Christie & Channon, 2014). Interventionists need to demonstrate a good quality MI to be able to interpret the outcomes with confidence, since practitioner proficiency was found to be associated with MI efficacy and client outcomes (Miller & Rollnick, 2013). The above applies to interventions that can distinguish the MI component in an intervention, but it becomes very challenging to evaluate fidelity to a specific intervention component when a hybrid of components exists (Miller & Rollnick, 2013).

Embedding discrete MI strategies (e.g., importance and confidence ratings) and using some of the skills (but out of an MI context) in practices or interventions (e.g., educational session) is not MI (Miller & Rollnick, 2009). MI is more complex than simply applying a set of disconnected techniques (Miller & Rollnick, 2009). Studies that included or were informed by MI and used discrete strategies and

techniques simply cannot be used to evaluate the efficacy of MI (e.g., CASCADE and DEPICTED).

Thus, there are limitations and contamination of results in studies constituting current evidence on the efficacy of MI for youth with diabetes. Meta-analyses and reviews of MI in the context of diabetes (and in health behaviour change in general) have urged addressing critical limitations to be able to scientifically evaluate the effect of MI in diabetes interventions (e.g., Christie & Channon, 2014; Gayes & Steele, 2014; Hampson et al., 2001; Martins & McNeil, 2009; Suarez & Mullins, 2008). The limitations that need to be addressed include: using validated and reliable measures to evaluate the fidelity of the delivered MI and to report data on the formal measures; outcome measures should include behavioural markers to assess changes in direct behaviours (e.g., SMOBG), as well as the psychosocial assessments and HbA1c; and the targeted population should comprise of youth with poorly controlled diabetes.

### **Significance, Aims, and Hypotheses of the Current Research**

Motivational Interviewing is a promising approach that has the potential to have a positive impact on diabetes outcomes. The currently tentative findings from previous research indicate its potential, but there is a lack in empirical-based evidence that examines MI as a standalone intervention for youth with poor diabetes control. Furthermore, none of these previous studies have evaluated the efficacy of MI with young adults (20-24 years old). This age group is important to study as it forms part of the emerging adult group of 18-25 year olds (Arnett, 2000, 2007). Diabetes management for emerging adults is at high risk of deterioration in the

transition to adulthood, and responsibility for diabetes self-management rests increasingly with the individual, and also in the transfer to adult diabetes care systems (Garvey, Markowitz, & Laffel, 2012; Lotstein et al., 2013; Peters, Laffel, & the American Diabetes Association Transitions Working Group, 2011). Emerging adults are therefore vulnerable for poor diabetes control, leading to adverse health outcomes, acute diabetes complications, and premature mortality (Garvey et al., 2012; Peters et al., 2011). Hence, the importance of research targeting this age group.

The primary objective of the current study was to evaluate the efficacy of MI as an intervention for youth (16-24 years old) with type 1 diabetes, who have poor glycaemic control ( $\text{HbA1c} > 64 \text{ mmol/mol}$ ). This level of glycaemic control suggests the need for more intensive intervention. This includes evaluating whether MI contributes to improved diabetes self-management, such as increased self-monitoring of blood glucose and insulin adjustment, as well as clinical improvement in the glycaemic control. Clinical, behavioural, and psychosocial measures were used to assess the intervention's efficacy. These include HbA1c, level of glycaemic variability, frequency of SMOBG, engagement in other diabetes self-management behaviours (e.g., insulin medication, timing and adjustment), and psychosocial questionnaires. A detailed section on the outcome measures is presented shortly. In addition, a formal treatment fidelity evaluation was conducted using the MITI 3.1 coding system.

This study aims to contribute to current knowledge and bridge some of the gaps in examining the efficacy of MI in interventions for youth with diabetes. This research aims to address some of the limitations in previous research to more clearly evaluate the efficacy of MI with youth with type 1 diabetes. This research is also the

first trial of MI with youth with type 1 diabetes in New Zealand.

Should the MI intervention be effective in improving diabetes self-management, this will have important positive health implications. As well as having the capacity to benefit the individual patients and their families, the study has the potential to be of benefit more broadly because many of the healthcare costs associated with diabetes stem from the complications arising from poorly controlled diabetes.

In the current study it was hypothesised that an MI intervention for youth with type 1 diabetes would have a positive impact on clinical, behavioural, and psychosocial measures. It was hypothesised that these improvements would be observed post-intervention, and then maintained at follow-up. The hypothesised improvements would be manifested by reduction in HbA1c post-intervention, reduction in the level of GV, increase in frequency of SMOBG, increased level of engagement in diabetes self-management behaviours, and improvement in psychosocial factors (i.e., illness perceptions, self-efficacy, and QoL).

## **Method**

### **Participants**

166 youth (16-24 years old) with type 1 diabetes in the CDHB catchment area were sent letters inviting their participation in the current study. The youth were identified from CDHB records as part of a larger study that was presented in Chapters 2 and 3 (Obaid et al., 2012a), which involved collating information about the youth from CDHB records from multiple electronic and physical sources,



including the most recent HbA1c. Potential participants were eligible to receive an invitation to take part in the current study if their most recent HbA1c was more than 64 mmol/mol. This level of metabolic control is considered unsatisfactory and may require additional intensive intervention. The selection of this cut off point was based on classification of diabetes control categories and previous research linking increased HbA1c to higher risks for diabetes complications (DCCT Research Group, 2002; Donaghue et al., 2009; NZSSD, 2009b). Individuals with type 1 diabetes who have high HbA1c are at an increased risk of having diabetes complications and this risk elevates with higher levels of HbA1c (DCCT Research Group, 1993; Fullerton et al., 2014; Nathan & Group, 2014; Nordwall et al., 2015). This group, compared to youth who have good metabolic control, are also more likely to need a multifaceted intervention (e.g., psychosocial and behavioural) to assist improving their diabetes control.

## **Research Design**

The current research used single-case experimental design, with a non-concurrent multiple-baseline design across participants. This design required at least three randomly selected participants identified as having poor diabetes control, in which each of the participants was randomly assigned to pre-determined baseline lengths of 3-5 weeks. The number of participants who agreed to take part in this study was  $N = 9$  (participants are described in the results section of this chapter). Each baseline period was assigned three participants. The distribution of participants to the pre-determined baseline and the designated intervention weeks are depicted in Table 4.1. Recruiting three participants in each baseline allowed for between person replication and in case participants drop out of the study.

**Table 4.1**

*Distribution of participants to the baseline and intervention weeks. The intervention weeks are 1, 2, 4, 8 weeks apart for each participant*

Baseline	Intervention week									
	1	2	3	4	5	6	7	8	9	10
3 weeks	3(S1)	3(S2)		3(S3)				3(S4)		
4 weeks		3(S1)	3(S2)		3(S3)				3(S4)	
5 weeks			3(S1)	3(S2)		3(S3)				3(S4)
Total <sup>+</sup>	3	6	6	6	3	3		3	3	3

*Note.* Si = Session number

<sup>+</sup>Total number of participants in the respective weeks

Single-case multiple-baseline experimental design has the advantage of enabling a new intervention to be trialled on a small number of participants, whilst still maintaining confidence that any observable changes can be attributed to the intervention by controlling for potential confounds (Horner et al., 2005; Watson & Workman, 1981). Put another way, this design enhances internal validity, which is the ability of the research design to rule out alternative explanations of the results (Horner et al., 2005). This design also minimises threats to internal validity by comparing results within- and between-participants, both during and after intervention, with each participant serving as his or her own control (Horner et al., 2005). Replication of the effects (i.e., intervention) across participants and using a range of different and intensive assessments of dependent variables (i.e., behavioural, psychosocial, and clinical outcomes) enhances the external validity of the results (Horner et al., 2005). Furthermore, the non-concurrent multiple-baseline design is experimental rather than correlational or descriptive, and it allows for the exploration of relationships between the independent variable and the dependent variables (Byiers, Reichle, & Symons, 2012; Horner et al., 2005).

## **Intervention**

The MI intervention comprised four individual sessions conducted over 8 weeks initiated at the end of each of the respective baseline periods. The average session duration was 41 minutes (range 25 to 60 minutes). After the intervention, follow up data were collected at 2 weeks, 3 months, 6 months, 9 months, and 12 months post-intervention. A booster MI session was provided after 6 months from the end of the MI intervention (mean length of booster sessions was 35 minutes, with a range 20 to 51 minutes).

The MI intervention and booster session were delivered by two experienced MI practitioners. One is a Registered Clinical Psychologist and the other is a Registered Nurse, both of whom hold a PhD and who are members of The Motivational Interviewing Network of Trainers (MINT), which is an international organisation of trainers in MI. Participants were randomly and evenly assigned to the interventionists for individual MI sessions. The sessions' dates were arranged with participants to suit their schedules; the sessions were spaced 1, 2, 4, and 8 weeks apart for each participant (Table 4.1 above). The location of the intervention sessions was at the Clinic of the School of Health Sciences Centre, University of Canterbury. All intervention sessions were audio-recorded.

## **Treatment fidelity**

Treatment fidelity was evaluated using the MITI 3.1.1 (Moyers, Martin, Manuel, Miller, & Ernst, 2010). A retrospective random sample of 30% of the recorded intervention sessions were sent to an MITI coding expert (a member of the MINT) based in the USA for independent evaluation (coding). The MITI is a reliable

and empirically validated tool designed to measure treatment integrity for clinical trials of MI and to provide feedback for training and clinical supervision (Jelsma et al., 2015). The MITI has a standard coding system and evaluation protocol for assessing relational and technical aspects of MI. The relational evaluation gives an overall impression of the interventionist's performance in terms of their communication style within a session, and is represented by 5-point global ratings. The global ratings encompass the MI-spirit, which includes autonomy, collaboration, and evocation as well as direction and empathy. A Global Clinician Rating score is calculated from the average of the autonomy, collaboration and evocation scale scores. An average of 4 or more on the MI-spirit indicates a competency level in delivering MI.

The technical aspects of MI are measured by behaviour counts. The behaviour counts represent a record of particular clinician behaviour instances during a session. The behaviours are classified into eight components: MI adherent (e.g., emphasise control and support), MI non-adherent (e.g., confronting and giving orders), giving information, questions (open or closed), and reflections (complex or simple). These behaviour counts are used to calculate summary scores, which are as follows. The percent of complex reflections (%CR), which is the number of complex reflections divided by of the total of all reflections; competency in MI requires complex reflections to be at least 50% of the total reflections. The percent of open questions (%OQ), which is the number of open questions divided by of the total of all questions; a percent of at least 70% indicates competency in MI. The reflection to question ratio (R:Q), which is the ratio of the total reflections to the total number of questions; a ratio of 2:1 is the minimum for achieving a competent level in MI. The

percent of adhering to MI (%MI-adherent), that is, the MI adherent counts divided by the total of MI adherent and non-adherent counts; a competency level in MI requires 100% adherence.

## Measures

Outcome measures in the current study are summarised as follows (see schematic representation and Table 4.2) and a description of each of these measures is presented in the following sections.

Primary outcome measures:

1. HbA1c at
  - a. pre-determined baseline period (baseline)
  - b. each of the follow-up points
2. Glycaemic variability was evaluated using blood glucose readings obtained from the participants SMOBG data at
  - a. baseline
  - b. intervention weeks

Secondary outcome measures (process variables):

1. Frequency of SMOBG provided by participants on weekly basis obtained from their blood glucose meters at
  - a. baseline
  - b. intervention weeks
  - c. each of the follow-up times
2. 24-hour (24hr) recall interview to measure adherence behaviours; Appendix 4.1 (Budde, 2009; Johnson, Silverstein, Rosenbloom, Carter, & Cunningham, 1986) was conducted at
  - a. baseline
  - b. intervention weeks
  - c. each of the follow-up times

and included:

- i. Insulin compliance,
    - a. insulin medication adherence, the total number of usage
    - b. insulin adjustment, total number of times insulin correctly adjusted
    - c. insulin timing, average time between meals and insulin usage
  - ii. Diet adherence, total number of meals and a bedtime snack (the number of carbohydrate servings eaten)
  - iii. Physical activity adherence, the frequency and type of exercise.
  - iv. SMOBG testing frequency
3. Psychosocial questionnaires, which included the same set used in Chapter 3 study.
- a. baseline
  - b. post-intervention
  - c. at each of the follow-up times

**Table 4.2***Outcome measures that were used to evaluate the efficacy of the MI intervention*

	Measure	Baseline	Intervention	Follow-up				
				2-Wk	3-M	6-M	9-M	12-M
<b>Primary outcome measures</b>	HbA1c	✓		✓	✓	✓	✓	✓
	Glycaemic variability	✓	✓					
<b>Secondary outcome measures</b>	SMOBG	✓	✓	✓	✓	✓	✓	✓
	Adherence <sup>+</sup> assessment	✓	✓	✓	✓	✓	✓	✓
	Psychosocial measures	✓		✓	✓	✓	✓	✓

*Note.* Wk = week; M=months; <sup>+</sup>24hr recall interview

### **Primary outcome measure: Blood glucose**

#### ***Glycated haemoglobin (HbA1c)***

HbA1c was used as a primary outcome measure and as an indicator of the level of diabetes control. This biomarker, as described in Chapter 1, is considered the gold-standard to monitor the progress of the diabetes condition, and the risk for developing diabetes-related complications (Bruns, 2007; Hanas et al., 2014). Baseline HbA1c was collected during the participants' assigned baseline (i.e., before the start of the intervention), and then post-intervention at each of the follow-up (i.e., 2-week, 3-month, 6-month, 9-month, and 12-month).

The HbA1c results were examined using statistical and clinical analyses. The clinical analysis was performed to examine the significance of changes in HbA1c in individual participants, from the latest baseline point to intervention and then at post-intervention points. A 0.5% (i.e., in IFCC units corresponds to at least 5 mmol/mol) change in HbA1c is considered clinically significant (Little et al., 2011). This level of change represents a meaningful change in HbA1c and it eliminates trivial changes due to biological or analytical variations (Little et al., 2011; Urrechaga, 2012). It also provides a reliable clinical significance threshold for determining whether diabetes control is stable, improving, or deteriorating (Little et al., 2011).

The HbA1c results were also examined using inferential statistics to evaluate statistical difference and equivalence in the study group data over time (i.e., from baseline to each follow-up). Inferential confidence intervals (ICI) were used to establish a modified 95% CI about each of two means (Tryon, 2001; Tryon & Lewis, 2008, 2009). The modified CIs are algebraically equivalent to a null hypothesis statistical test between two means, and provide context for expanding on the alternative hypothesis (Tryon, 2001; Tryon & Lewis, 2008). The ICI can be used to examine whether two means are equivalent, that is, ICIs provide means for inferring on equivalence in two means rather than only accepting or rejecting the null hypothesis if the means are not different at an alpha level of .05 (e.g., such as in ANOVA comparisons).

The ICI results can be interpreted based on three main cases. The first case is when the ICIs do not overlap; the results are then statistically significant and the means are different from each other. The second case, which is statistical equivalence, is when the maximum probable difference estimate (i.e., the upper CI



limit of the greater mean minus the lower CI limit of the lesser mean) fits within an inconsequential difference between the two CIs. The inconsequential difference can be based on a delta ( $\Delta$ ) bound of the maximum difference that can be dismissed on substantive ground. The coefficient of variation (CV) for HbA1c was used to calculate delta, thereby accounting for biological variation amongst participants (Fraser, 2001). The HbA1c CV is 5.6% (Gomes et al., 2001; Westgard, 2014), and the delta corresponds to the maximum change in baseline mean that is considered insignificant (i.e.,  $CV \times \text{baseline HbA1c}$ ). Appendix 4.2 illustrates how ICIs were calculated to evaluate statistical difference and equivalence, the significance level was 0.05 (which corresponds to 95% CI). The third case, which is statistical indeterminacy, is when the means are neither statistically different nor equivalent. Evidence for or against cannot be drawn in the case of the statistical indeterminacy, and therefore conclusions about results must be suspended until further investigations (Tryon, 2001).

The effect sizes for the statistically significant results were calculated using Cohen's  $d$  (Cohen, 1992), which is the difference between mean baseline and follow-up results divided by the standard deviation of the mean score at baseline. The magnitude of the effect was interpreted using Cohen's (1997) guidelines, with  $d = 0.2$  representing a small effect,  $d = 0.5$  a moderate effect, and  $d = 0.8$  a large effect.

### ***Glycaemic variability***

Glycaemic variability (GV) was assessed to evaluate whether there were any changes in blood glucose oscillation profiles and their level of stability over time during baseline and intervention. Instability of blood glucose and long-term episodes

of hypoglycaemia and hyperglycaemia are associated with an increased risk for developing diabetes-related complications (Kilpatrick, 2009; Krishna et al., 2013; Robeva et al., 2007). The evaluation of GV provides information on the quality of blood glucose profiles and may account for the frequency and severity level of hypoglycaemia and hyperglycaemia excursions (i.e., mild, moderate, or severe excursions) (Dailey, 2007; Kovatchev et al., 2000; Kovatchev et al., 2006).

There are several methods to measure GV from SMOBG data. These include basic mathematical calculations (e.g., mean and standard deviation, and coefficient of variation), and advanced mathematical methods such as: mean amplitude of glycaemic excursions (MAGE), mean daily difference (MDD), glycaemic risk assessment diabetes equation (GRADE), and liability index (LI) (Tylee & Trence, 2012). In the context of GV, there has been criticism in the literature of the basic averaging of data and standard deviation and its derivatives (DeVries, 2013; Satya Krishna, Kota, & Modi, 2013). The validity of results from these simple methods may have an impact from the violations in the underlying assumptions that relate to the normal distribution, whereby the blood glucose data distribution is naturally asymmetric and breaches the Gaussian shape attributes (Kovatchev, Cox, Gonder-Frederick, & Clarke, 1997). In contrast, the advanced GV assessment methods, although complicated in their mathematical representations and outcomes in quantifying GV, have several drawbacks. They have an inherited bias towards hyperglycaemia readings, are insensitive to hypoglycaemia readings, and their results may also be affected by the asymmetry of the blood glucose data distribution (Kovatchev et al., 2006; Ruiz de Adana, Domínguez-López, Tapia, González, & Soriguer, 2008). Alternative new measures have emerged to overcome some of these

limitations: measures such as low blood glucose index (LBGI), high blood glucose index (HBGI), and average daily risk range (ADRR) (Kovatchev et al., 1998; Kovatchev et al., 2000; Kovatchev et al., 2006). Studies validating and using these measures have found them reliable and more accurate than the previously introduced variability measures (Kovatchev et al., 1998; Kovatchev et al., 2006; Patton & Clements, 2013). They also have an advantage of being independent of the diabetes type and the number of blood glucose readings per day (Kovatchev et al., 2006; Robeva et al., 2007).

The ADRR, LBGI, and HBGI measures use normalisation and mathematical procedures to derive a symmetrical scale that has transformed blood glucose values (Kovatchev et al., 1997; Kovatchev et al., 1998; Kovatchev et al., 2000; Kovatchev et al., 2006). The procedures are outlined shortly and the formal equations are presented in Appendix 4.3. The underlying concept of these measures is to convert the blood glucose readings into risk values, in which each blood glucose reading is transformed and then given a risk weight, depending on where the raw value lies on the actual blood glucose scale. The symmetrisation of the actual blood glucose scale involves using mathematical transformation such that the target range is transformed to have zero at its centre, which is mapped to 6.25 mmol/L on the actual blood glucose scale. Transformed values on either side of this centre are given a sign and a numerical weight. The left side values are given a negative sign and the right side values are given a positive sign. The transformed blood glucose values  $f(BG)$  are then converted into risk values using the risk function  $r(BG)$ , which represent the risk associated with different blood glucose levels and have a value from 0 to 100. The LBGI is computed from the left branch of the processed values, whereas the HBGI is

computed from the right branch values. The computed indices in the separate branches are summed and then divided by the total number of blood glucose readings (i.e., averaged), yielding an aggregated risk value for each of LBGI and HBGI.

The LBGI is a measure of the risk of hypoglycaemia accounting for the frequency and severity of hypoglycaemia, and it is independent of the hyperglycaemic episodes (Kovatchev et al., 1998; Kovatchev et al., 2000; Kovatchev et al., 2003). In contrast, HBGI is independent of the hypoglycaemic episodes and it provides a measure of the risk of hyperglycaemia accounting for the frequency and severity of hyperglycaemia (Kovatchev, Cox, Gonder-Frederick, & Clarke, 2002; Kovatchev et al., 2000; Kovatchev et al., 2006). Empirical research has led to the derivation of stratified levels of blood glucose risks values and these categories represent the degree of risks for future hypoglycaemia and hyperglycaemia episodes (Kovatchev et al., 2000; Kovatchev et al., 2003). The LBGI has the following risk categories: *minimal* ( $\text{LBGI} \leq 1.1$ ), *low* ( $1.1 < \text{LBGI} \leq 2.5$ ), *moderate* ( $2.5 < \text{LBGI} \leq 5$ ), and *high* ( $\text{LBGI} > 5$ ) (Kovatchev et al., 2003); and HBGI has the following risk categories: *low* ( $\text{HBGI} \leq 4.5$ ), *moderate* ( $4.5 < \text{HBGI} \leq 9$ ), and *high* ( $\text{HBGI} > 9$ ) (Kovatchev et al., 2000). The accuracy of outcomes from LBGI and HBGI can be optimised by using a recommended minimum number of blood glucose readings; approximately 130 blood glucose readings collected over 4 to 5 weeks is recommended (Kovatchev et al., 1998; Kovatchev et al., 2000; Kovatchev et al., 2003). The original research, which used 50 blood glucose readings collected over 2 to 3 weeks, however, suggests that valid outcomes can be achieved with fewer readings and over a shorter time frame (Cox et al., 1994; Kovatchev et al., 1998). In current study, the LBGI and HBGI were calculated using these guidelines and

previously outlined mathematical procedure (Appendix 4.3). Four out of the seven participants (Participants B, C, D, and F), in this study, had more than 130 readings in each of the baseline and intervention periods. The remaining two participants (Participants A and E) had more than 50, but less than 130, readings in each of the baseline and intervention periods.

The LBGi and HBGI, as mentioned previously, were designed to be specifically sensitive to hypoglycaemia and hyperglycaemia, respectively. They measure the level of risk associated with deviations from the clinical target range, with progressive weight accounting for the extent of the excursions. Each of the LBGi and HBGI is a unique measure that is specific to evaluating (respectively) the low and high glycaemic levels, and cannot be simply combined to provide an assessment of a complete profile (i.e., having both the low and high blood glucose fluctuations). A single measure that could analyse the overall quality of the fluctuations in a blood glucose profile and capture long-term trends for predicting dangerously significant blood glucose oscillations would be useful (Kovatchev et al., 2006). Studies suggest that highly variable and unstable blood glucose may be associated with the risk of acute diabetes complications, including physiological complications (Krishna et al., 2013; Trence & Hirsch, 2012; Tylee & Trence, 2012). The quantified overall GV, using a single measure, could be used to indicate risks for future significant glycaemic episodes. A combined measure, equally sensitive to both hypoglycaemia and hyperglycaemia, was derived to evaluate GV and to quantify the degree of risk for significant excursions. A mathematically combined left and right side branches of the risk functions  $r(BG)$ , Appendix 4.3, were used in the new assessment measure calculations: ADRR (Kovatchev et al., 2006).

The ADRR is a measure of the average daily risk range which assesses GV and the degree of risk for future extreme excursions. The measure takes into account the frequency and extent of the glycaemic excursions and assigns risk values accordingly. The values of ADRR were classified into four categories: low risk ( $\text{ADRR} < 20$ ), low-moderate risk ( $20 \leq \text{ADRR} < 30$ ), moderate-high risk ( $30 \leq \text{ADRR} \leq 40$ ), and high risk ( $\text{ADRR} > 40$ ) (Kovatchev, 2012; Kovatchev et al., 2006). The ADRR can be calculated from consecutive or non-consecutive days, where there are at least three readings per day within a period of 30 days. The authors indicated that the minimum required number of days to obtain reliable results is 14 (Kovatchev et al., 2006). In the current study, the days rule ( $14 < \text{days} < 30$ , and 3 readings per day) was applied, and in case of more than 30 days in each of the periods, only the last 30 days were used. The majority of participants had at least three readings per day in at least 14 days within a month in each of the baseline and intervention periods<sup>3</sup>. In addition to being consistent across participants, in line with the ADRR underlying mechanism, the outlined method is also considered sufficient to reflect reliably the current diabetes management status in each of the baseline and intervention periods in terms of glycaemic excursions and to quantify the degree of risk for future glycaemia (Kovatchev et al., 2006).

The ADRR score in conjunction with specific LBG and HBGI scores provided the means to analyse blood glucose profiles obtained from SMOBG. The former provided information on the GV as a whole, in terms of assessing the quality

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<sup>3</sup> The Participant E had 11 days within five weeks that included readings which are at least three per day.

of the blood fluctuations, the extent of the different excursions, and the degree of risk for having future instability in the blood glucose profile. The latter two provided specific information on directions and degree of that causing the instability of blood glucose profile, that is, hypoglycaemia, or hyperglycaemia, or both. Outcomes from these measures were compared from baseline to intervention, and checked for any patterns across participants. The participants' follow-up blood glucose profiles lacked a sufficient number of data points to reliably carry out the analysis; this is because the GV section of this thesis was added after data collection had finished. Future studies could consider adding an adequate protocol so that sufficient data are collected for GV analysis during follow-up.

### **Secondary outcome measures: Psychosocial questionnaires**

The secondary outcome measures comprised a set of psychosocial questionnaires to measure changes in illness perceptions, self-efficacy and QoL. The questionnaires were BIPQ, CIDS, and PedsQL 3.2, and were the same set of questionnaires that were used in the cross-sectional study of this thesis (Chapter 3). The measures were described previously in Chapter 3, and have shown adequate reliability and suitability to use in this thesis. The measures were administered to participants at baseline and then post-intervention at each of the follow-ups (i.e., 2-week, 3-month, 6-month, 9-month, and 12-month).

The questionnaire data were analysed by clinical and statistical analytical procedures to examine changes in the individual and the group data over time. These procedures required identifying a minimal clinically important difference (MCID) (Cook, 2008; Hilliard et al., 2013). The MCID is identified based on calculating a

value beyond which (increase or decrease) is considered meaningful and that is not due to a measurement error (Cook, 2008; Harvill, 1991; McManus, 2012). The standard error of measurement (SEM) was used to determine MCID; meaningful variations in scores need to be equal to, or greater than, SEM (Harvill, 1991; Hilliard et al., 2013; Wyrwich, Tierney, & Wolinsky, 1999). The SEM was estimated using a questionnaire's reliability coefficient (e.g., Cronbach alpha) and a questionnaire's *SD* of a normative sample (i.e.,  $SEM = SD * \sqrt{1 - \alpha}$ ) (Harvill, 1991; Hilliard et al., 2013; Wyrwich et al., 1999). Data from the cross-sectional study of this thesis (Chapter 3) provided a normative platform to estimate the MCID for the current study analyses, as an MCID for each of the questionnaires (i.e., BIPQ, CIDS, and PedsQL 3.2) was not available in the literature. The only existing MCID relevant to the current study, was presented in research by Hilliard et al. (2013), was for the PedsQL 3.0 but not for PedsQL 3.2, and the latter is the version used in the current study.

The group data analysis involved using ICIs to evaluate statistical difference and equivalence. The ICI procedures were described earlier in the *Measures* section in this chapter. The delta was set to SEM to account for inconsequential difference resulting from measurement errors. Additionally, the effect size was calculated for any statistically significant result (Cohen, 1992).

Changes in an individual participant's questionnaire data were examined using reliable change index (RCI) (Jacobson & Truax, 1991). The RCI procedure determined whether the changes were clinically significant, that is, the RCI determined if a change in score were due to a real change or a chance variation (Jacobson & Truax, 1991; Zahra & Hedge, 2010). The RCI was estimated by



calculating the difference of two data points (e.g.,  $X_{BL}$  = score at baseline and  $X_{Follow-up}$  = score at follow-up) and then dividing the result by the standard error of difference ( $S_{diff}$ ) between the scores. The  $S_{diff}$  is estimated using SEM, such that  $S_{diff} = \text{Sqrt}(2) * \text{SEM}$  (Jacobson & Truax, 1991). The  $S_{diff}$  describes the spread of the distribution of the difference scores. An RCI greater than 1.96 in absolute value would be unlikely to occur ( $p < 0.05$ ) without actual change, which suggests a clinically significant change in score.

### **Secondary outcome measures: Adherence recall interview**

Adherence has proven difficult for researchers to measure due to the complexity of the different aspects of the diabetes medical regimen, its individuality amongst patients, and reliance on self-report (Budde, 2009; McNabb, 1997; Rudell, Thrift-Perry, Savre, Perret, & Caron, 2012). Researchers have previously assessed adherence using self-report questionnaires (e.g., SDSCA), SMOBG, and the 24hr recall interview (Budde, 2009). The current study used the latter two to assess adherence. Increased frequency of SMOBG was found to be associated with reduction in HbA1c, and is considered a core adherence component (Schutt et al., 2006). The 24hr recall interview provided a measure for other essential adherence components.

The 24hr recall interview assesses adherence related to the diabetes medical regime and lifestyle adjustments (Johnson et al. 1986). A modified version of the 24hr recall interview (also referred to as *recall interview*), which was adapted by Budde (2009), was used in the current study. The modified recall interview incorporated two additional components: insulin adjustment and weekly SMOBG

frequency. The recall interview assessed adherence to the following essential adherence behaviours: diet frequency, SMOBG frequency, insulin frequency, insulin timing, insulin adjustment, and exercise frequency.

Recall interview data (i.e., diet frequency, SMOBG frequency, insulin frequency, insulin timing, and insulin adjustment) were collected once a week on a random day. The participants were randomly called on a weekly basis throughout the baseline and intervention periods, and then once at each follow-up. The 24hr recall items were recorded from the previous day from the time when a participant got up until the time he or she went to bed.

The score on each adherence component is the total number of *Yes* boxes checked (See Appendix 4.1: 24hr recall interview). A specific number of yes checks is needed to meet an *acceptable level* of adherence. The adherence assessment and the acceptable levels in the current study were guided by adherence recommendations in New Zealand on diabetes management (CDHB, 2015; Diabetes New Zealand, 2014; Reed, 2014), which were equivalent to those found in Budde (2009). The acceptable levels provide a general guide of what might be ideal for individuals with type 1 diabetes, especially those struggling with diabetes control. Hence, in the context of the current study any consistent improvement in adherence was positively perceived even if the acceptable levels were not met. Changes in adherence behaviours over time were evaluated graphically. Data analysis involved visual inspections of graphs to identify patterns across participants and to check changes in adherence behaviours in individual participants.

The adherence components are defined as follows (Budde, 2009). Diet

frequency was defined as the total number of meals (i.e., breakfast, lunch and dinner) plus a bedtime snack. The SMOBG frequency was defined as the total number of blood glucose tests at the three meals and before bedtime. Insulin frequency was defined as the total number of insulin doses at the three meals and before bedtime. A score of four was considered the acceptable level for each of diet, SMOBG, and insulin frequency. Insulin timing was estimated using the time elapsed between the insulin dose and meal time, which needed to be at most 15 minutes apart. Hence, 15 minutes was subtracted from the reported insulin timing and an average time was calculated, whereby zero minutes is considered to be the acceptable timing average. The insulin adjustment frequency referred to the number of times the correct amount of insulin was taken at the three meals. The acceptable level for insulin adjustment was three, indicating that at each meal time the participant took the correct amount of insulin, according to her or his blood glucose level and number of carbohydrate units consumed.

Weekly data (i.e., physical activity and objective SMOBG) were also collected throughout baseline and intervention, and during a week close to each follow-up. The physical activity was recalled using a 7-day chart that was filled out by participants on a weekly basis. Twenty minutes of physical activity three times a week was considered the minimum acceptable level. The weekly SMOBG data (tabulated) were provided by participants from their blood glucose meters. A frequency of 28 was considered the minimum acceptable level of SMOBG per week, equating to four daily tests per week. The weekly SMOBG actual blood glucose readings were used to analyse GV, as outlined previously.

## Results

Results are presented as follows:

- Participants' characteristics
- Treatment fidelity
- Primary outcome measure:
  - HbA1c\*
  - GV
- Secondary outcome measures:
  - Psychosocial questionnaires\*
  - Adherence assessment: 24hr recall interview

\* The results of the group data (i.e., statistical tests) will be presented first, followed by the individual data (including evaluation of clinically significant change).

### Participants' Characteristics

Of the 166 youth contacted regarding participation in the current study, nine agreed to participate and had a record of a recent HbA1c. Table 4.3 outlines the descriptive characteristics of those who completed the study, those who withdrew at baseline, or at a later stage during the intervention.

**Table 4.3**

*Characteristics of participants during the MI intervention study*

		Accepted	Withdrew in baseline	Withdrew during study	Completed
Gender	Male	3	1	0	2
	Female	6	1	2	3
Ethnicity	European	9	2	2	5
Age (years)	<i>M</i>	19.8	20	20.5	19.4
	Range	(18-23)	(18; 22)	(18; 23)	(18-22)

All of the participants who agreed to take part in the study were European, with an average age of 19.8 years, and with more females ( $n = 6$ ) than males ( $n = 3$ ). Two participants withdrew at baseline: one participant aged 22 did not engage in the baseline data collection, and the other participant aged 18 chose not to continue because of being very busy during the time of the study. Two further participants withdrew after the start of the intervention and during follow-up. One of these participants (aged 23 years) moved to Auckland and withdrew just after the 2-weeks follow-up. The other participant (aged 18 years) was planning to travel overseas and withdrew just after her third MI session because of time pressures. The two participants who withdrew from the study after the commencement of the intervention agreed that the researcher could obtain HbA1c data through their GP for the remainder of the study. Five participants (females = 3, males = 2) with an age range of 18 to 22 (average 19.4 years) completed the intervention.

### **Treatment Fidelity**

All of the audio recordings reviewed by the independent MITI coder met the threshold for competency, which provided evidence to suggest that that it was MI that was being delivered, and also that the MI was delivered with a high level of skill (Table 4.4).

**Table 4.4**

*Fidelity – average summary scores on the MITI 3.1.1 from a sample of 30% of sessions*

Measure	Rating/percentage
Global clinician rating	5
Reflection to Question Ratio (R:Q)	2
Percent Open Questions (%OC)	72%
Percent Complex Reflections (%CR)	56%
Percent MI-Adherent (% MIA)	100%

### **Primary Outcome Measure: Blood Glucose**

#### **Glycated haemoglobin (HbA1c)**

##### ***Statistical tests of group data***

The HbA1c results were not statistically equivalent at baseline and during follow-up (Table 4.5). The results tended to be the same or slightly higher than at baseline and all of the follow-up assessments. The difference, however, was not statistically significant. Hence, because the results were neither equivalent nor different this resulted in statistical indeterminacy and suspension of conclusion about the findings (Tryon, 2001).

**Table 4.5***HbA1c means, inferential confidence intervals and results of statistical tests*

Time	<i>M</i>	<i>r</i>	95% CI	Different	Equivalent $\Delta \approx 4$ mmol/mol
Baseline	70.50		67.77 - 73.23		
2-week follow-up	70.83	0.310	66.24 - 75.42	<i>ns</i>	<i>ns</i>
Baseline	71.00		67.36 - 74.64		
3-month follow-up	74.40	0.191	68.93 - 79.87	<i>ns</i>	<i>ns</i>
Baseline	71.00		68.94 - 73.06		
6-month follow-up	74.80	0.798	71.71 - 77.89	<i>ns</i>	<i>ns</i>
Baseline	70.50		67.59 - 73.41		
9-month follow-up	74.50	0.271	68.55 - 80.45	<i>ns</i>	<i>ns</i>
Baseline	71.75		69.05 - 74.45		
12-month follow-up	71.75	0.999	66.08 - 77.42	<i>ns</i>	<i>ns</i>

*Note.**r* = Pearson's correlation $\Delta$  = 1 CV of baseline mean

\* = statistically significant at .05 level

*ns* = not statistically significant at .05 level***Clinically significant change in individual data***

Results from the HbA1c individual data, investigating clinically significant changes from baseline to each follow-up, are presented in Table 4.6 and Figure 4.2. It should be noted that pre- and post-intervention data were non-concurrently collected for participants. Data collection occurred during their assigned baseline and at subsequent follow-up. The graphs show relative time points from start of intervention and at each follow-up. The observed results for Participant A showed he had a clinically significant increase from baseline to the 2-week follow-up, which was maintained during the 6-month and 9-month follow-up. Participant B had a clinically significant increase at the 6-month follow-up, his HbA1c, however, did not show any

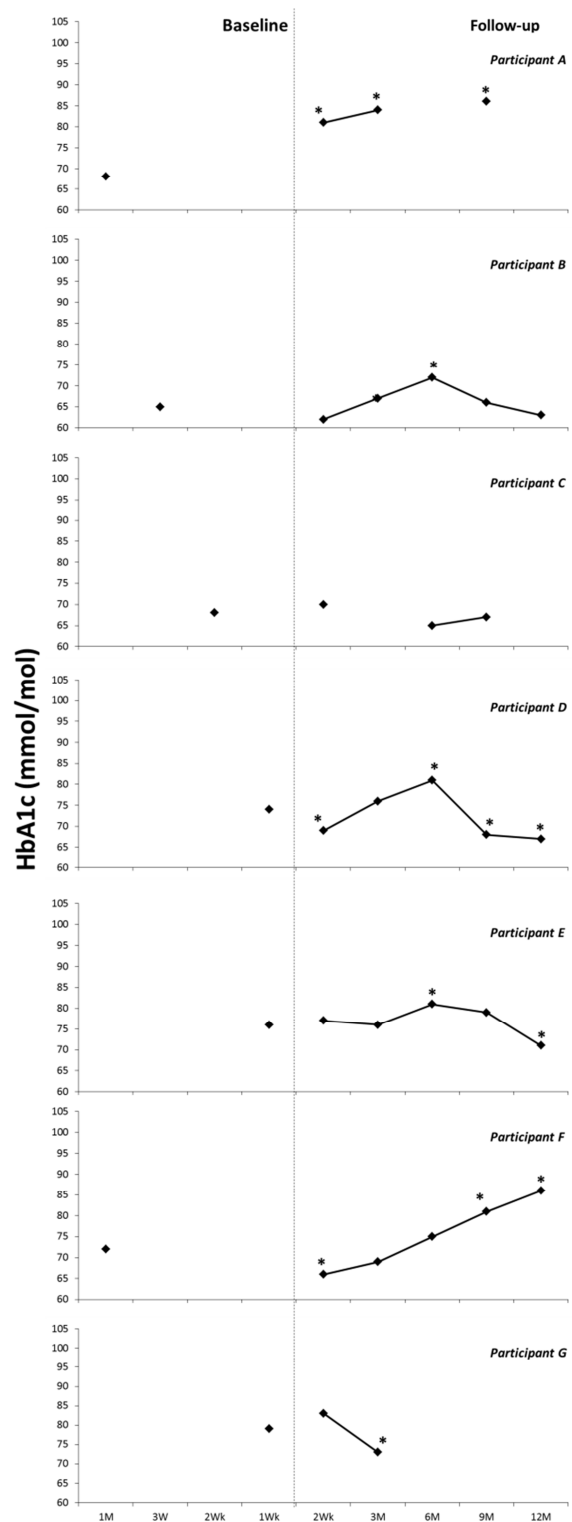
clinically significant change during the other follow-up (2-week, 3-month, 9-month, and 12-month) assessments. Participant C had no clinically significant change in HbA1c from baseline to the follow-up assessments (2-week, 3-month, and 6-month). Participant D had a clinically significant decrease in HbA1c at the 2-week follow-up, then a clinically significant increase at the 6-month follow-up. This participant also had a clinically significant decrease at the 9-month and 12-month follow-up, which suggests improvements in HbA1c during the latter part of follow-up, after the significant increase at 6 months (Table 4.6). Participant E had a stable HbA1c during the 2-week and 3-month follow-up, then a significant increase at the 6-month follow-up followed by a non-significant decrease in HbA1c at the 9-month, then a clinically significant decrease at the 12-month follow-up. Participant F had a clinically significant drop at the 2-week follow-up, then a trend of increasing HbA1c that had two clinically significant increases at the 9-month and 12-month follow-up. Participant G had no changes at the 2-week follow-up, followed by a significant decrease at the 3-month follow-up.



**Table 4.6***Clinically significant change in HbA1c individual data*

Participant	Follow-up				
	2-week	3-month	6-month	9-month	12-month
A	+13	+16	<i>m</i>	+18	<i>m</i>
B			+7		
C <sup>^</sup>		<i>m</i>			<i>m</i>
D	−5		+7	−6	−7
E			+5		−5
F	−6			+9	+14
G <sup>^^</sup>		−6	<i>m</i>	<i>m</i>	<i>m</i>

*Note.*− = clinically significant decrease from baseline (i.e.,  $|\text{reading}_2 - \text{reading}_1| \geq 5\text{mmol/mol}$ )+ = clinically significant increase from baseline (i.e.,  $|\text{reading}_2 - \text{reading}_1| \geq 5\text{mmol/mol}$ )<sup>^</sup> Participant C withdrew from the study upon the 2-week follow-up. After seeking permission from the participant, HbA1c blood test results were accessed through her GPs.<sup>^^</sup> Participant G withdrew from the study just after the third MI session. After seeking the participant's permission, HbA1c readings were sought through her GP. The 3-month HbA1c reading was the only available reading for that patient post the intervention*m* = missing HbA1c; empty cell means there was no clinically significant change from baseline.



**Figure 4.2.** Results from HbA1c. \* = Clinically significant change (i.e.,  $|\text{reading}_2 - \text{reading}_1| \geq 5$  mmol/mol). Wk = week and M = month. The HbA1c targets for acceptable and optimal diabetes control are, respectively, 55-64 mmol and  $< 55$  mmol/mol.

In summary, Participant D was the only participant who had a clinically significant decrease post intervention that was maintained during the 9-month and 12-month follow-up, despite a clinically significant increase at the 6-month follow-up. It can be noted that three of four participants (Participants B, D, and E) who had data at the 6-month follow-up had a trend of an increasing HbA1c at the 6-month follow-up, and then a drop in HbA1c in the subsequent follow-ups (9-month and 12-month). The decrease in HbA1c resulted in either a close value to that at baseline (Participant B) or a clinically significant decrease (Participants D and E). It should be noted here the participants had their booster session at the 6-month follow-up, changes in HbA1c results are expected to show months post the booster session (i.e., at or after 9 months), because HbA1c measures the average blood glucose of the past 2-3 months.

Finally, although there was a clinically significant decrease in HbA1c for some of the cases throughout the follow-up, none of the participants post intervention achieved targets for optimal glycaemic control ( $< 55$  mmol/mol). Nonetheless, the three participants who had a downtrend post the booster session achieved a lower HbA1c (from baseline) that was approaching or at the upper limit of acceptable range (i.e., 64mmol/mol).

### **Glycaemic Variability**

Results from ADRR, LBG1, and HBGI are presented in Table 4.7 and Appendix 4.4 presents the SMOBG charts. The categories and corresponding scores across participants in Table 4.7, from baseline to intervention, generally indicated an improvement in terms of the ADRR and HBGI risk outcomes. Furthermore, the

LBGI categories were maintained in the low risk range but with varying scores, except for one participant who had a category change from low to moderate risk.

**Table 4.7**

*Results from SMOBG analysis of LBGI (indicates risk for hypoglycaemic excursions), HBGI (indicates risk for hyperglycaemic excursions), and the ADRR (reflects the risk for glucose variability).*

Participant	Measure	Baseline (score)	Intervention (score)
A	ADRR	Moderate-high risk (38)	Low-moderate risk (21.1)
	LBGI	Moderate risk (3)	Low risk (1.4)
	HBGI	High risk (11.6)	Moderate risk (7.6)
B	ADRR	High risk (47.1)	Moderate-high risk (38.8)
	LBGI	Low risk (1.4)	Low risk (0.9)
	HBGI	High risk (19.7)	High risk (19.6)
C	ADRR	High risk (45.2)	High risk (42.4)
	LBGI	Low risk (0.6)	Low risk (0.6)
	HBGI	High risk (21.2)	High risk (19.6)
D	ADRR	Moderate-high risk (35.7)	Moderate-high risk (37.1)
	LBGI	Low risk (2.1)	Moderate risk (3.3)
	HBGI	High risk (11)	High risk (10.6)
E	ADRR	High risk (59.7)	High risk (53.1)
	LBGI	Low risk (1.6)	Low risk (2)
	HBGI	High risk (28.5)	High risk (22.9)
F	ADRR	Low-moderate risk (25.8)	Low-moderate risk (20.3)
	LBGI	Low risk (0.6)	Low risk (2.1)
	HBGI	High risk (12.6)	Moderate risk (5.1)

Two participants (Participants A and B) had a considerable drop in scores, from baseline to intervention, which downgraded the ADRR category to a lower risk grade. This downgrade indicates a lower risk for having extreme glycaemic excursions and suggests a comparatively more stable GV than that in the higher category. The severity of the GV manifested by the ADRR scores was also reduced for the majority of the remainder participants, but a risk category change was not observed. Score reductions suggest an improved GV profile and less frequent extreme excursions, whereas a score increase indicates a less stable blood glucose

profile and more extreme glycaemic excursions.

The LBGI results varied amongst participants. Participant A had a reduction in the score and LBGI risk category, which indicated he had a lower risk for hypoglycaemia from baseline to intervention. Participant B also had a reduction in the LBGI score and remained in the same category of a low level risk. Participant C's score was maintained in the very low risk range (approaching zero) from baseline to intervention. Two of the remaining participants (Participants E and F) had an increase in the LBGI scores, which indicates a greater risk for hypoglycaemia, yet they were still categorised in the low risk range. Participant D, however, had an increase in the LBGI score indicating an increase in the risk for hypoglycaemia.

The HBGI category was changed for two of the participants, and the remainder of participants had some degree of reduction in the score but not in the grade. Participant A and Participant F had a large decrease that downgraded the risk level from high to moderate risk, indicating a substantial decrease in the frequency of hyperglycaemia episodes during the study. The HBGI score for the remainder of participants also decreased from baseline to intervention, indicating a reduced risk for hyperglycaemia, but the decrease was not sufficient for a category change. The decrease in score suggested less extreme elevated blood glucose and fewer hyperglycaemic episodes.

### **Secondary Outcome Measures: Psychosocial Measures**

Statistical comparisons for each psychosocial measure are made within groups across time from baseline to each follow-up (i.e., 2-week, 3-month, 6-month, 9-month and 12-month). Questionnaire data were missing the two participants who

withdrew from the study (Participants C and G), but Participant C provided the 2-week follow-up data and this was included in the analysis. Additionally, some participants did not complete the questionnaires at various times during follow-up: Participant F at the 9-month and 12-month follow-up, and Participant A at the 12-month follow-up.

### **Statistical tests of group data**

#### ***Quality of life: PedsQL***

The PedsQL total score results are presented first, and then the five PedsQL dimensions results are presented separately (i.e., *About my diabetes*, *Treatment I*, *Treatment II*, *Worry*, and *Communication*). There was a statistically significant increase in the total score of the PedsQL scale during follow-up, with the exception of the 9-month follow-up (Table 4.8). The largest increase in the PedsQL total score was observed from baseline to the 3-month follow-up, with a moderate-to-high effect size ( $d = 0.72$ ). The remaining effect sizes corresponding to the statistically significant increases in the PedsQL total score were also moderate:  $d = 0.52$ ,  $0.51$ ,  $0.49$ , in order, at the 2-week, 6-month and 12-month follow-up from baseline. The increase in the scores suggested an improved diabetes-specific QoL indicating that diabetes became less problematic over time, from baseline up to the 12-month follow-up point. The results of the 9-month follow-up were neither statistically equivalent nor different than baseline, resulting in statistical indeterminacy.

**Table 4.8***PedsQL total score means, inferential confidence intervals and results of statistical tests*

Time	<i>M</i>	<i>r</i>	95% CI	Different	Equivalent $\Delta = 3.98$
Baseline	55.74		52.76 - 58.73		
2-week follow-up	64.65	0.952	62.00 - 67.30	*	<i>ns</i>
Baseline	57.05		50.11 - 63.98		
3-month follow-up	70.76	0.895	66.06 - 75.46	*	<i>ns</i>
Baseline	57.05		52.74 - 61.35		
6-month follow-up	66.67	0.95	61.46 - 71.88	*	<i>ns</i>
Baseline	58.62		52.46 - 64.77		
9-month follow-up	68.56	0.935	62.55 - 74.57	<i>ns</i>	<i>ns</i>
Baseline	53.16		48.61 - 57.71		
12-month follow-up	64.14	0.987	59.68 - 68.60	*	<i>ns</i>

*Note.**r* = Pearson's correlation $\Delta$  = MCID

\* = statistically significant at .05 level

*ns* = not statistically significant at .05 level

The PedsQL *About my diabetes* (diabetes symptoms) results (Table 4.9) during follow-up, with the exception of 2-week follow-up, were statistically significantly higher than baseline, with a moderate effect size ( $d = 0.42, 0.48, 0.5$ , and  $0.41$ , respectively). Higher scores indicate lower problems associated with diabetes symptoms and QoL. This suggests the participants were experiencing fewer problems with diabetes symptoms. The 2-week follow-up results were statistically indeterminate in relation to baseline.

**Table 4.9**

*PedsQL About my diabetes score means, inferential confidence intervals and results of statistical tests*

Time	<i>M</i>	<i>r</i>	95% CI	Different	Equivalent $\Delta = 4.94$
Baseline	53.89		49.68 - 58.09		
2 weeks post-intervention	61.11	0.904	57.92 - 64.30	<i>ns</i>	<i>ns</i>
Baseline	54.33		51.86 - 56.80		
3-month follow-up	61.67	0.977	59.38 - 63.96	*	<i>ns</i>
Baseline	54.33		50.98 - 57.68		
6-month follow-up	62.67	0.957	59.63 - 65.70	*	<i>ns</i>
Baseline	54.17		49.39 - 58.94		
9-month follow-up	64.17	0.965	60.02 - 68.32	*	<i>ns</i>
Baseline	47.78		45.27 - 50.29		
12-month follow-up	55.56	0.999	53.29 - 57.82	*	<i>ns</i>

*Note.*

*r* = Pearson's correlation

$\Delta$  = MCID

\* = statistically significant at .05 level

*ns* = not statistically significant at .05 level

The *PedsQL Treatment I* (treatment barriers) results during follow-up were not statistically equivalent to baseline, but also were not statistically different, resulting in statistical indeterminacy (Table 4.10). The scores, however, tended to be higher than that at baseline, suggesting a trend to fewer personal and social problems related to treatment (e.g., pain from finger pricks and insulin shots, arguments with parents or partners about diabetes care, and feeling embarrassed by their diabetes treatment).



**Table 4.10***PedsQL Treatment I means, inferential confidence intervals and results of statistical tests*

Time	<i>M</i>	<i>r</i>	95% CI	Different	Equivalent $\Delta = 7.98$
Baseline	61.25		54.41 - 68.09		
2 weeks post-intervention	71.67	0.776	64.19 - 79.14	<i>ns</i>	<i>ns</i>
Baseline	64.50		55.97 - 73.03		
3-month follow-up	80.00	0.758	71.76 - 88.24	<i>ns</i>	<i>ns</i>
Baseline	64.50		58.43 - 70.57		
6-month follow-up	77.00	0.889	69.90 - 84.10	<i>ns</i>	<i>ns</i>
Baseline	63.13		50.26 - 75.99		
9-month follow-up	78.75	0.747	67.22 - 90.28	<i>ns</i>	<i>ns</i>
Baseline	54.17		37.81 - 70.52		
12-month follow-up	75.00	0.710	62.00 - 88.00	<i>ns</i>	<i>ns</i>

*Note.**r* = Pearson's correlation $\Delta$  = MCID

\* = statistically significant at .05 level

*ns* = not statistically significant at .05 level

The PedsQL *Treatment II* (treatment adherence) results during follow-up were not statistically equivalent to baseline, but also were not statistically different, resulting in statistical indeterminacy (Table 4.11). The scores, however, were all higher than those at baseline, suggesting a trend to fewer problems related to treatment adherence (e.g., taking blood glucose tests and insulin medication, keeping track of carbohydrates, and doing physical activity).

**Table 4.11***PedsQL Treatment II means, inferential confidence intervals and results of statistical tests*

Time	<i>M</i>	<i>r</i>	95% CI	Different	Equivalent $\Delta = 9.44$
Baseline	61.11		53.73 - 68.49		
2-week follow-up	65.28	0.895	59.69 - 70.87	<i>ns</i>	<i>ns</i>
Baseline	60.00		40.55 - 79.44		
3-month follow-up	67.50	0.433	47.31 - 87.69	<i>ns</i>	<i>ns</i>
Baseline	60.00		53.18 - 66.82		
6-month follow-up	61.67	0.954	53.15 - 70.19	<i>ns</i>	<i>ns</i>
Baseline	65.62		57.85 - 73.39		
9-month follow-up	64.58	0.957	55.78 - 73.39	<i>ns</i>	<i>ns</i>
Baseline	59.72		54.03 - 65.41		
12-month follow-up	66.67	0.996	60.41 - 72.93	<i>ns</i>	<i>ns</i>

*Note.**r* = Pearson's correlation $\Delta$  = MCID

\* = statistically significant at .05 level

*ns* = not statistically significant at .05 level

The *PedsQL Worry* (worries about diabetes complications) results during follow-up, with the exception of 3-month follow-up, were statistically significantly higher than baseline (Table 4.12). The effect size was large at each of the follow-ups that had a statistically significant result (2-week, 6-month, 9-month, and 12-month):  $d = 0.79, 1.2, 0.86, \text{ and } 0.88$ , respectively. These results suggest that through most of the follow-up period (except at the 3-month follow-up) participants had fewer problems associated with worries about diabetes complications. At the 3-month follow-up, however, the results were statistically indeterminate in relation to baseline

despite the increase in the score from baseline.

**Table 4.12**

*PedsQL Worry means, inferential confidence intervals and results of statistical tests*

Time	<i>M</i>	<i>r</i>	95% CI	Different	Equivalent $\Delta = 13.08$
Baseline	33.33		27.11 - 39.55		
2-week follow-up	51.39	0.925	42.55 - 60.23	*	<i>ns</i>
Baseline	35.00		10.69 - 59.31		
3-month follow-up	75.00	-0.194	54.56 - 95.44	<i>ns</i>	<i>ns</i>
Baseline	35.00		28.13 - 41.87		
6-month follow-up	65.00	0.934	56.17 - 73.83	*	<i>ns</i>
Baseline	39.58		24.89 - 54.28		
9-month follow-up	62.50	0.932	54.55 - 70.45	*	<i>ns</i>
Baseline	36.11		29.65 - 42.57		
12-month follow-up	63.89	0.999	58.4 - 69.37	*	<i>ns</i>

*Note.*

*r* = Pearson's correlation

$\Delta$  = MCID

\* = statistically significant at .05 level

*ns* = not statistically significant at .05 level

The PedsQL *Communication* results (at each of the five follow-ups) were not statistically equivalent to baseline, but also were not statistically different, resulting in statistical indeterminacy (Table 4.13). The scores, however, tended to be higher than those at baseline, suggesting a trend to fewer problems with regards to diabetes-related communication, such as asking questions and conveying feelings about diabetes to nurses and doctors, and explaining their diabetes to other people.

**Table 4.13***PedsQL Communication means, inferential confidence intervals and results of statistical tests*

Time	<i>M</i>	<i>r</i>	95% CI	Different	Equivalent $\Delta = 10.73$
Baseline	64.58		58.58 - 77.25		
2-week follow-up	78.13	0.863	72.1 - 84.15	*	<i>ns</i>
Baseline	70.0		50.53 - 89.47		
3-month follow-up	95.0	-0.088	88.15 - 101.85	<i>ns</i>	<i>ns</i>
Baseline	70.0		61.02 - 78.98		
6-month follow-up	77.5	0.808	63.58 - 91.42	<i>ns</i>	<i>ns</i>
Baseline	73.44		60.79 - 86.09		
9-month follow-up	82.81	0.728	66.76 - 98.86	<i>ns</i>	<i>ns</i>
Baseline	75.0		55.59 - 94.41		
12-month follow-up	79.17	0.866	51.15 - 107.19	<i>ns</i>	<i>ns</i>

*Note.**r* = Pearson's correlation $\Delta$  = MCID

\* = statistically significant at .05 level

*ns* = not statistically significant at .05 level***Illness perceptions: BIPQ***

The BIPQ results during follow-up, with the exception of the 9-month and 12-month follow-up, were statistically significantly lower than baseline, with a moderate effect size:  $d = 0.43, 0.51$ , and  $0.64$ , respectively (Table 4.14). These suggest diabetes became viewed as being a less threatening condition. At the 9-month and 12-month follow-up, however, the results were statistically indeterminate in relation to baseline.

**Table 4.14***BIPQ means, inferential confidence intervals and results of statistical tests*

Time	<i>M</i>	<i>r</i>	95% CI	Different	Equivalent $\Delta = 2.78$
Baseline	56.46		54.98 - 57.94		
2-week follow-up	51.56	0.972	49.98 - 53.15	*	<i>ns</i>
Baseline	55.00		53.69 - 56.31		
3-month follow-up	48.75	0.995	47.61 - 49.89	*	<i>ns</i>
Baseline	55.00		52.42 - 57.58		
6-month follow-up	47.13	0.986	43.65 - 50.60	*	<i>ns</i>
Baseline	53.75		48.00 - 59.50		
9-month follow-up	47.19	0.866	40.85 - 53.53	<i>ns</i>	<i>ns</i>
Baseline	56.25		52.60 - 59.9		
12-month follow-up	53.33	0.991	49.17 - 57.50	<i>ns</i>	<i>ns</i>

*Note.**r* = Pearson's correlation $\Delta$  = MCID

\* = statistically significant at .05 level

*ns* = not statistically significant at .05 level***Self-efficacy: CIDS***

The CIDS results during follow-up, with the exception of the 2-week follow-up (Table 4.15), were statistically significantly higher than baseline, with effect sizes that were moderate-to-large:  $d = 0.74, 0.92, 1.03$ , and  $0.78$ , respectively. These results suggest that the participants during most of the follow-up experienced increased confidence in their ability to carry out diabetes self-care tasks. At the 2-week follow-up, however, the results were statistically indeterminate in relation to baseline.

**Table 4.15***CIDS means, inferential confidence intervals and results of statistical*

Time	<i>M</i>	<i>r</i>	95% CI	Different	Equivalent $\Delta = 4.410$
Baseline	68.75		60.26 - 77.25		
2-week follow-up	74.63	0.308	64.32 - 84.94	<i>ns</i>	<i>ns</i>
Baseline	66.07		61.4 - 70.75		
3-month follow-up	75.95	0.847	71.76 - 80.15	*	<i>ns</i>
Baseline	66.07		61.07 - 71.07		
6-month follow-up	78.33	0.848	71.89 - 84.78	*	<i>ns</i>
Baseline	63.69		62.45 - 64.93		
9-month follow-up	78.27	0.998	77.14 - 79.4	*	<i>ns</i>
Baseline	61.91		56.25 - 67.57		
12-month follow-up	75.00	0.993	67.77 - 82.23	*	<i>ns</i>

*Note.**r*=Pearson's correlation $\Delta$  = MCID

\* = statistically significant at .05 level

*ns* = not statistically significant at .05 level**Clinically significant change**

The clinically significant changes ( $|RC| > 1.96$ ) in the questionnaires scores from baseline are presented in Tables 4.16-4.18 and Figures 4.3-4.7. An empty cell in the tables indicates that there was no clinically significant change in the score from baseline. The direction of change is identified by the digit sign and is interpreted according to the corresponding questionnaire's guideline. The positive sign indicates an increase that is clinically significant from baseline, whereas the negative sign indicates a decrease that is clinically significant from baseline. The missing data

include the 9-month and 12-month questionnaires data for Participant F, and the 12-month data for Participant A. Participant C had data up to the 2-week follow-up, which is just before she withdrew from the study, and Participant G did not have any follow-up data available as she withdrew from the study just after the third MI session. It should also be noted that pre- and post-intervention data were non-concurrently collected for participants. This occurred during their assigned baseline and at subsequent follow-up. The graphs show relative time points from start of intervention and at each follow-up.

### ***Illness perception: BIPQ***

The BIPQ score, for all of the participants, did not have clinically significant changes from baseline, and therefore a table or a figure was not depicted.

### ***Self-efficacy: CIDS***

There were clinically significant changes in the CIDS scores from baseline to follow-up (Table 4.16 and Figure 4.3). An increase in the CIDS score suggests an improvement in the confidence (belief) in the ability to carry out diabetes self-care tasks, whereas a decrease in the score suggests the opposite. At the 2-week follow-up, three participants (Participants A, B, and E) had a clinically significant increase in their confidence in the ability to carry out diabetes self-care tasks. Yet one participant (Participant F) experienced a decrease in this, which suggests that she was less confident than she had been at baseline. Participant A and Participant B maintained their improved confidence level throughout the follow-up. At the 6-month follow-up, Participant D also had an increased CIDS score which was maintained at the 9-month

and 12-month follow-up, suggesting that the improvement in confidence to carry out diabetes self-care tasks was maintained.

**Table 4.16**

*Clinically significant change on the CIDS scale*

Participant	Follow-up				
	2Wk	3M	6M	9M	12M
A	+3.05	+3.05	+2.86	+2.10	<i>m</i>
B	+2.77	+2.10	+3.43	+2.29	+2.67
C		<i>m</i>	<i>m</i>	<i>m</i>	<i>m</i>
D			+2.67	+2.29	+2.48
E	+2.67			+2.67	
F	−4.49			<i>m</i>	<i>m</i>

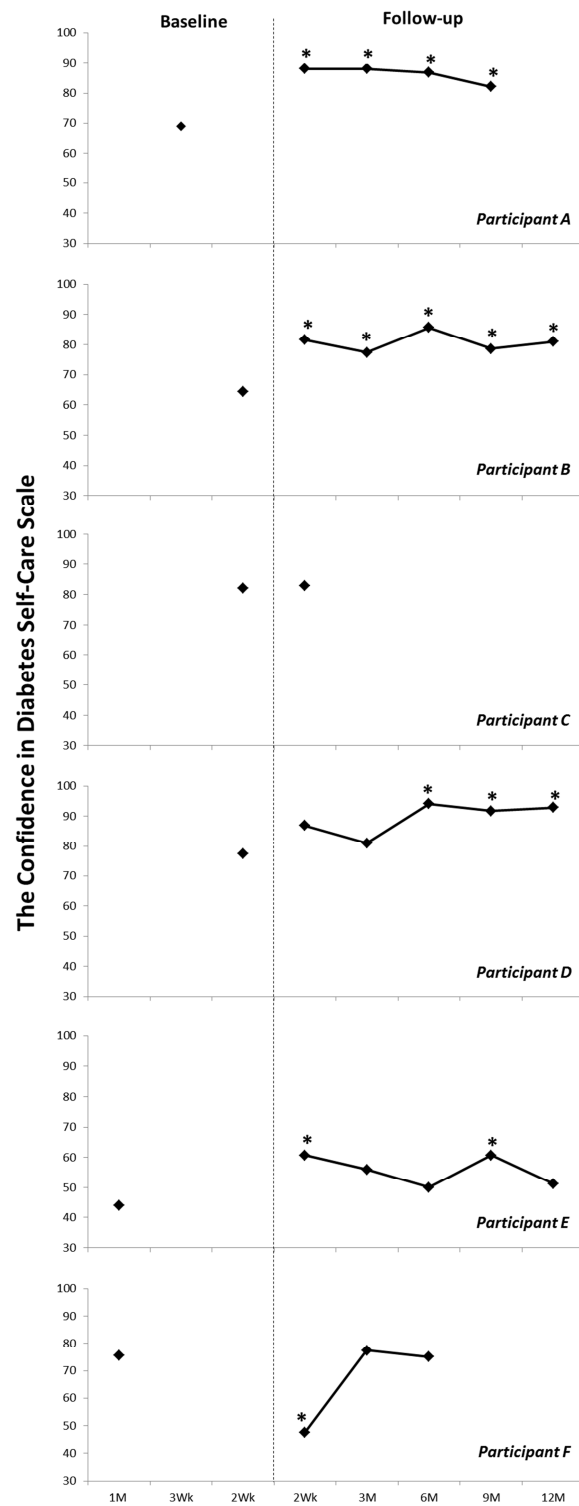
*Note.*

+ = clinically significant increase in score (i.e.,  $|RC| > 1.96$ ) from baseline

− = clinically significant decrease in score (i.e.,  $|RC| > 1.96$ ) from baseline

*m* = missing; empty cell means there was no clinically significant change in the score from baseline





**Figure 4.3.** The CIDS mean scores at baseline and follow-up. \* = Clinically significant change (i.e.,  $|\text{reading}_2 - \text{reading}_1| \geq 4.41$ ), M = month, and Wk = week.

### ***Quality of life: PedsQL***

The majority of participants had an improved PedsQL total score during follow-up (Table 4.17 and Figure 4.4), which suggests fewer problems related to diabetes-specific QoL. Participant D had a clinically significant increase in the PedsQL total score from baseline throughout follow-up. This participant also had a further clinically significant improvement at the 6-month follow-up, compared to that at earlier follow-up (i.e., 2-week and 3-month) from baseline, which was maintained at the 9-month follow-up point. Participant B had an improved PedsQL total score that was maintained throughout follow-up. Participant E had an improvement in the PedsQL total score from baseline to the 2-week follow-up, a further improvement at the 3-month follow-up, and maintained improved scores from baseline to the 9-month and 12-month follow-up. Participant F's score was improved at the 3-month follow-up, and maintained an improvement at the 6-month follow-up from baseline.

**Table 4.17**

*Clinically significant change on the PedsQL total score*

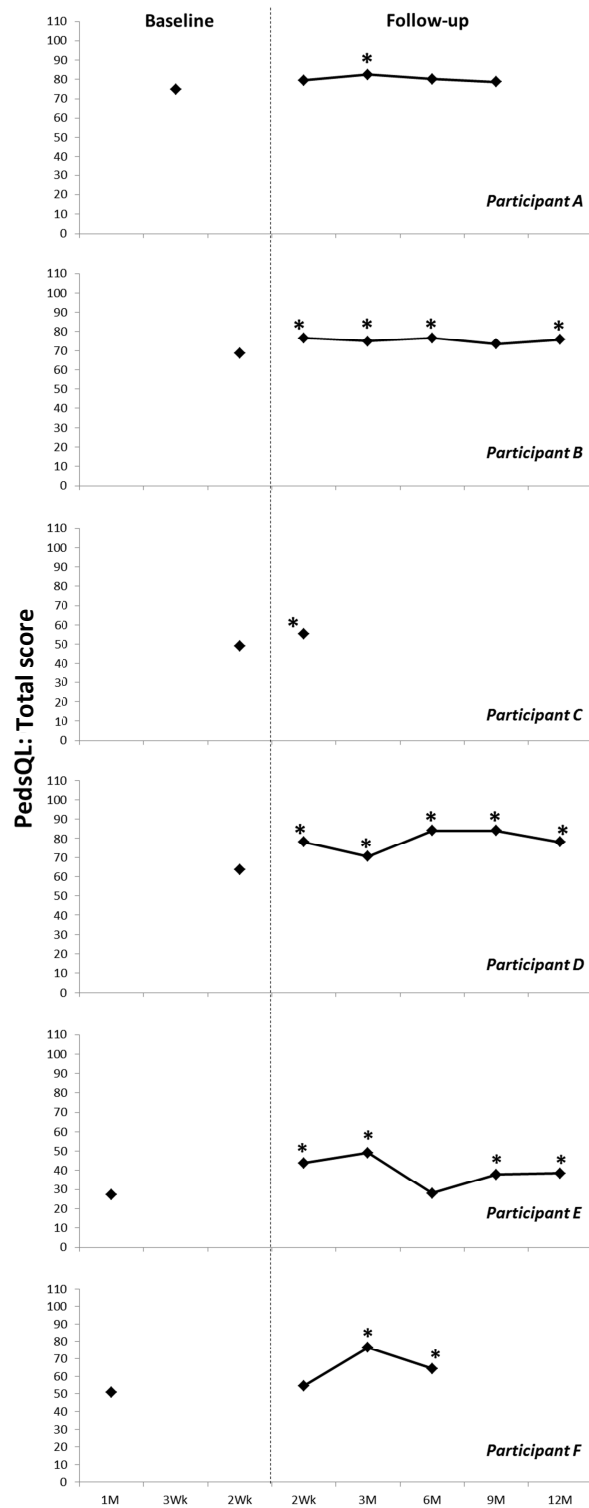
Participant	Follow-up				
	2Wk	3M	6M	9M	12M
A		+2.69			<i>m</i>
B	+2.82	+2.28	+2.82		+2.55
C	+2.15	<i>m</i>	<i>m</i>	<i>m</i>	<i>m</i>
D	+5.10	+2.42	+7.25	+7.25	+5.10
E	+5.91	+7.79		+3.76	+4.03
F		+9.13	+4.83	<i>m</i>	<i>m</i>

*Note.*

+ = clinically significant increase in score (i.e.,  $|RC| > 1.96$ ) from baseline

– = clinically significant decrease in score (i.e.,  $|RC| > 1.96$ ) from baseline

*m* = missing; empty cell means there was no clinically significant change in the score from baseline



**Figure 4.4.** The PedsQL total mean scores at baseline and follow-up. \* = Clinically significant change (i.e.,  $|\text{reading}_2 - \text{reading}_1| \geq 3.98$ ), M = month, and Wk = week.

Clinically significant changes in the PedsQL five dimensions (i.e., *About my diabetes*, *Treatment I*, *Treatment II*, *Worry*, and *Communication*) are presented in Table 4.18 and Figures 4.5-4.7. Two participants had clinically significant improvements in the PedsQL *About my diabetes* score. The score increased for Participant E at the 2-week follow-up and for Participant D it increased at the 9-month follow-up. The results suggest that diabetes symptoms (e.g., feeling dizzy, shaky, and sweaty) became less problematic for these two participants. Three participants (Participants D, E, and F) had a clinically significant increase in the PedsQL *Treatment I* score at follow-up, which suggests they experienced fewer problems associated with diabetes treatment barriers (e.g., pain from insulin shot or figure prick, and arguing with partner/parents about diabetes care). Participant D had an increased *PedsQL Treatment I* score from baseline which was maintained throughout the follow-up (i.e., 2-week, 3-month, 6-month, 9-month, and 12-month). Participant E had an increased score at the 12-month follow-up, and Participant F had an increased score at the 3-month follow-up. The PedsQL *Treatment II* score had not improved for most of the study participants, except for Participant F at the 3-month follow-up. This result suggests that Participant F had fewer problems with her treatment adherence (e.g., taking blood glucose tests, keeping track of carbohydrates, and exercising) at the 3-month follow-up. The PedsQL *Worry* score clinically significantly increased for three cases (Participants A, D, and E) during follow-up, indicating fewer problems associated with worries about diabetes complications. Participant A had an improved *Worry* score at the 3-month follow-up. Participant D experienced fewer worries during the 2-week post-intervention and 6-month follow-up. Participant E experienced fewer worries related to diabetes complications during the 3-month and 9-month follow-up. The PedsQL *Communication* score clinically significantly

increased for two participants (Participants F and E), a 3-month follow-up, suggesting better communication related to their diabetes (e.g., telling the doctor or nurses how they feel and asking questions, explaining their illness to other people). Participant E, however, had a clinically significant decrease in this score at the 6-month follow-up, from baseline, indicating more problems related to communication.

**Table 4.18***Clinically significant change on the five dimensions of the PedsQL scale*

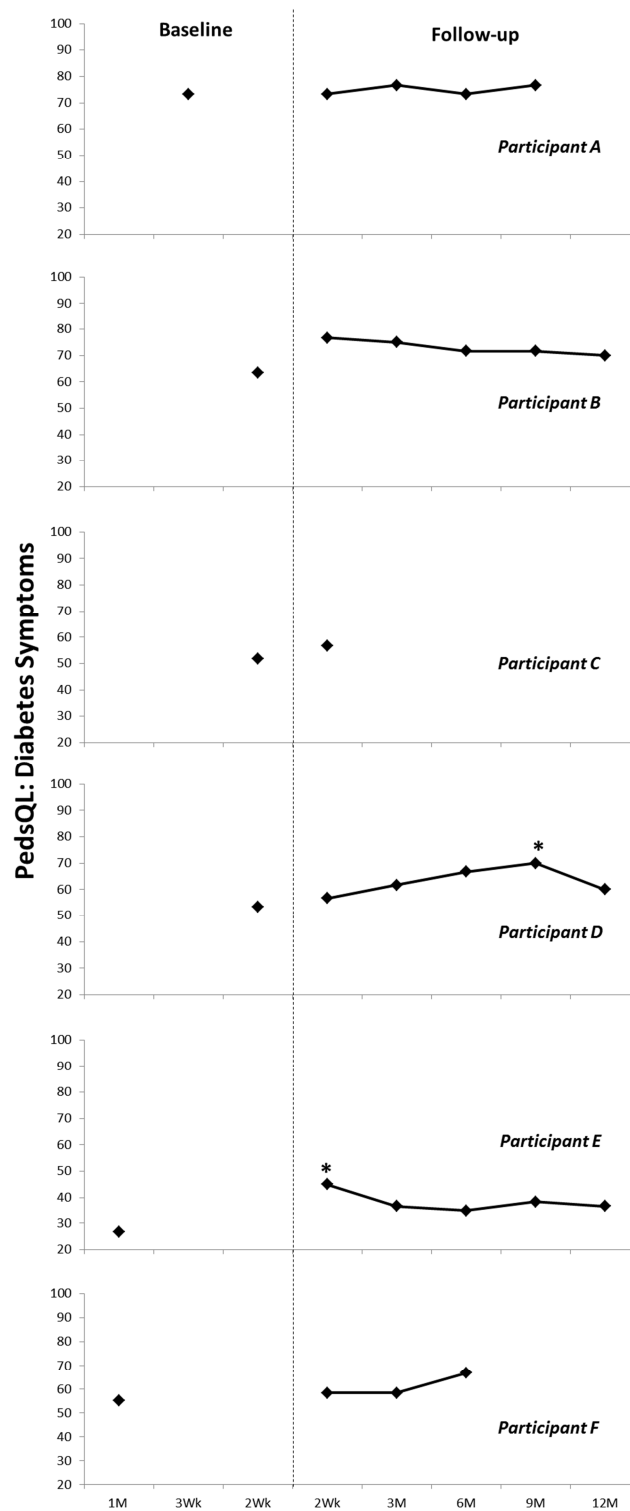
Scale	Participant	Follow-up				
		2Wk	3M	6M	9M	12M
<i>PedsQL About Diabetes</i>	A					<i>m</i>
	B					
	C		<i>m</i>	<i>m</i>	<i>m</i>	<i>m</i>
	D				+2.38	
	E	+2.62				
	F				<i>m</i>	<i>m</i>
<i>Treatment I</i>	A					<i>m</i>
	B					
	C		<i>m</i>	<i>m</i>	<i>m</i>	<i>m</i>
	D	+2.66	+2.21	+2.66	+3.1	+2.21
	E					+2.66
	F		+2.66		<i>m</i>	<i>m</i>
<i>Treatment II</i>	A					<i>m</i>
	B					
	C		<i>m</i>	<i>m</i>	<i>m</i>	<i>m</i>
	D					
	E					
	F		+4.68		<i>m</i>	<i>m</i>
<i>Worry</i>	A		+2.25			<i>m</i>
	B					
	C		<i>m</i>	<i>m</i>	<i>m</i>	<i>m</i>
	D	+2.25		+2.7		
	E		+5.41		+2.25	
	F				<i>m</i>	<i>m</i>
<i>Communication</i>	A					<i>m</i>
	B					
	C		<i>m</i>	<i>m</i>	<i>m</i>	<i>m</i>
	D					
	E		+3.29	-2.06		
	F		+2.88		<i>m</i>	<i>m</i>

*Note.*

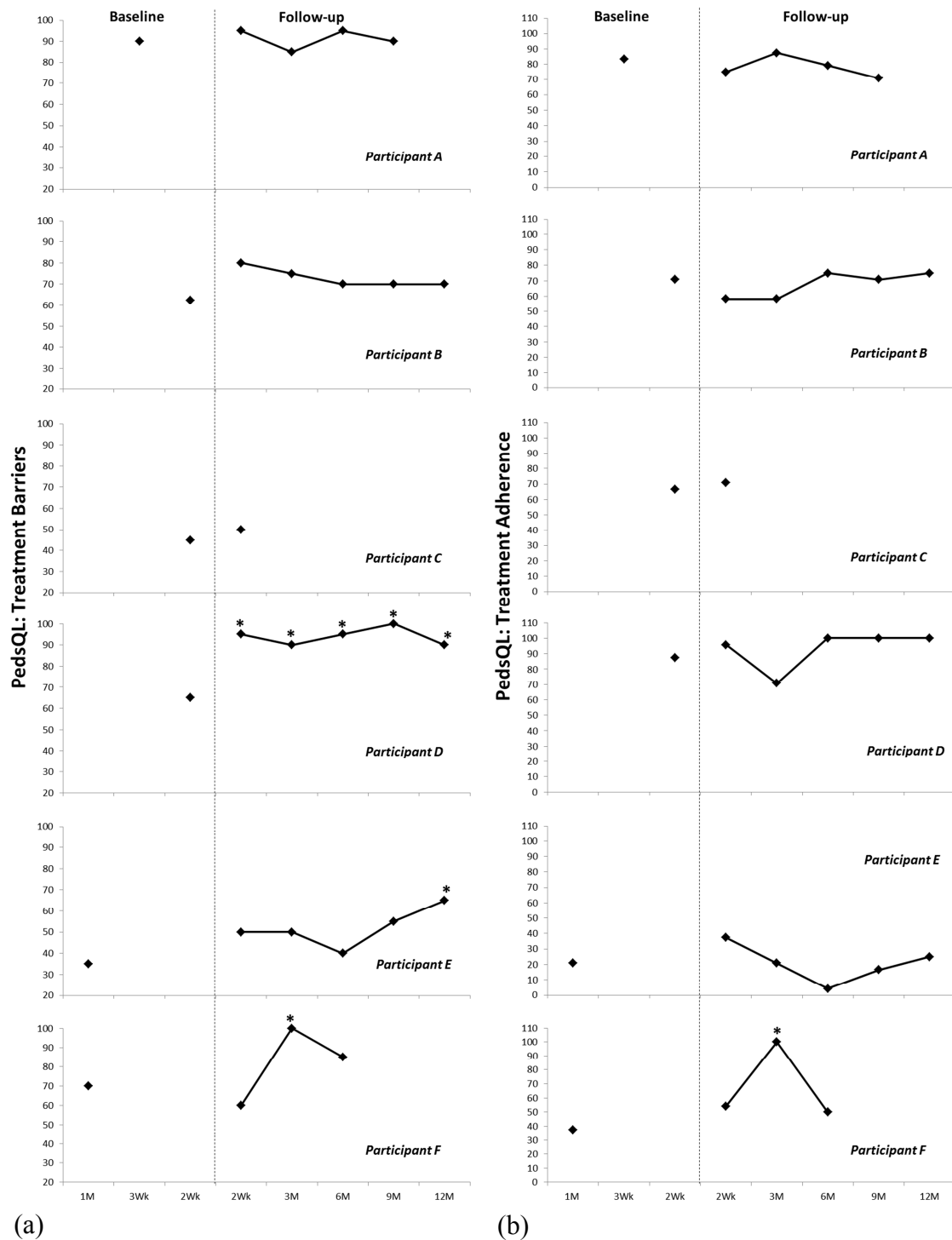
+ = clinically significant increase in score (i.e., |RC| &gt; 1.96) from baseline

- = clinically significant decrease in score (i.e., |RC| &gt; 1.96) from baseline

*m* = missing; empty cell means there was no clinically significant change in the score from baseline

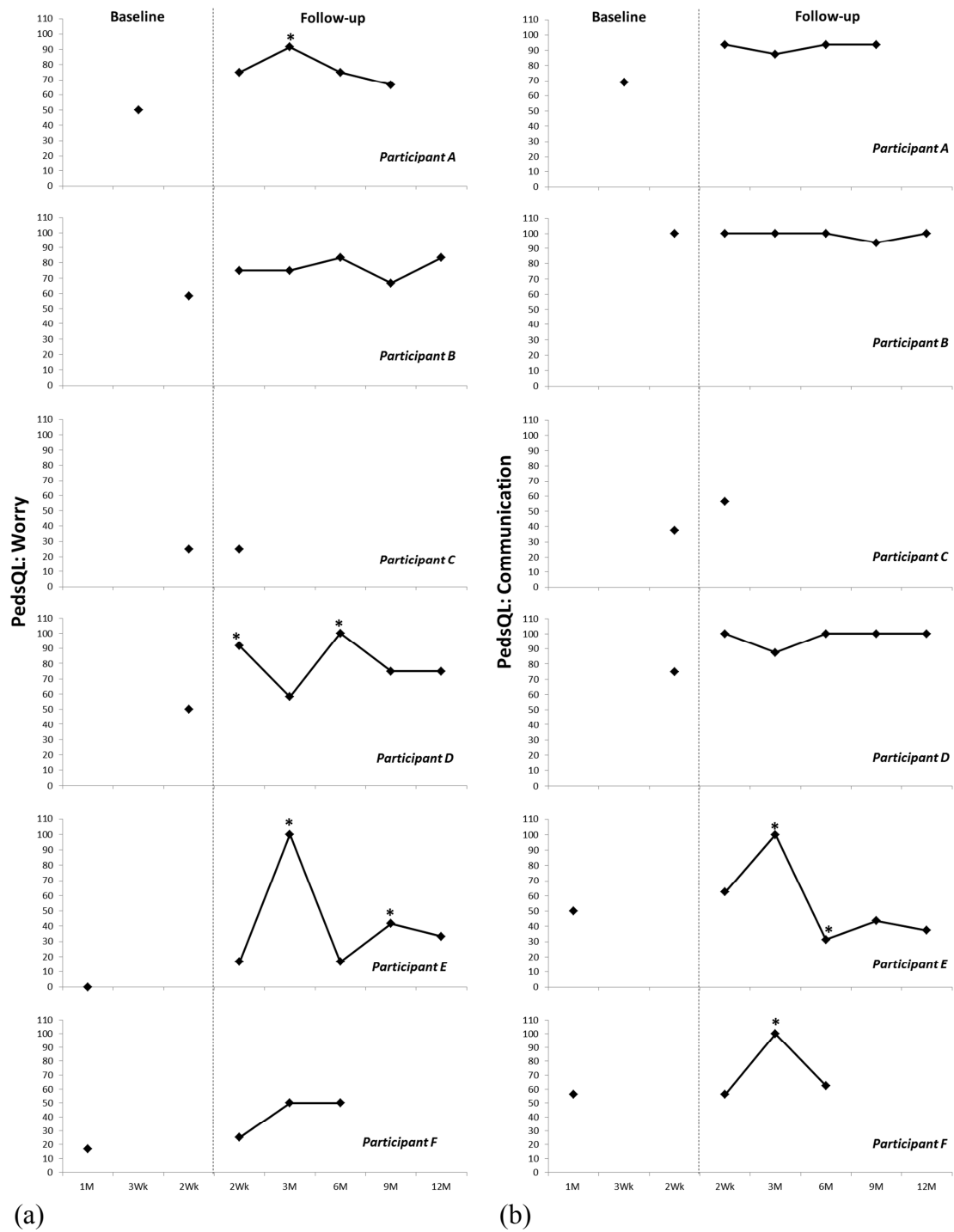


**Figure 4.5.** The PedsQL Diabetes Symptoms mean scores at baseline and follow-up. \* = Clinically significant change (i.e.,  $|\text{reading}_2 - \text{reading}_1| \geq 4.94$ ), M = month, and Wk = week.



**Figure 4.6.** The PedsQL (a) Treatment Barriers and (b) Treatment Adherence mean scores at baseline and follow-up. \* = Clinically significant change (i.e.,  $|\text{reading}_2 - \text{reading}_1| \geq$  (a) 7.98, (b) 9.44), M = month, and Wk = week.



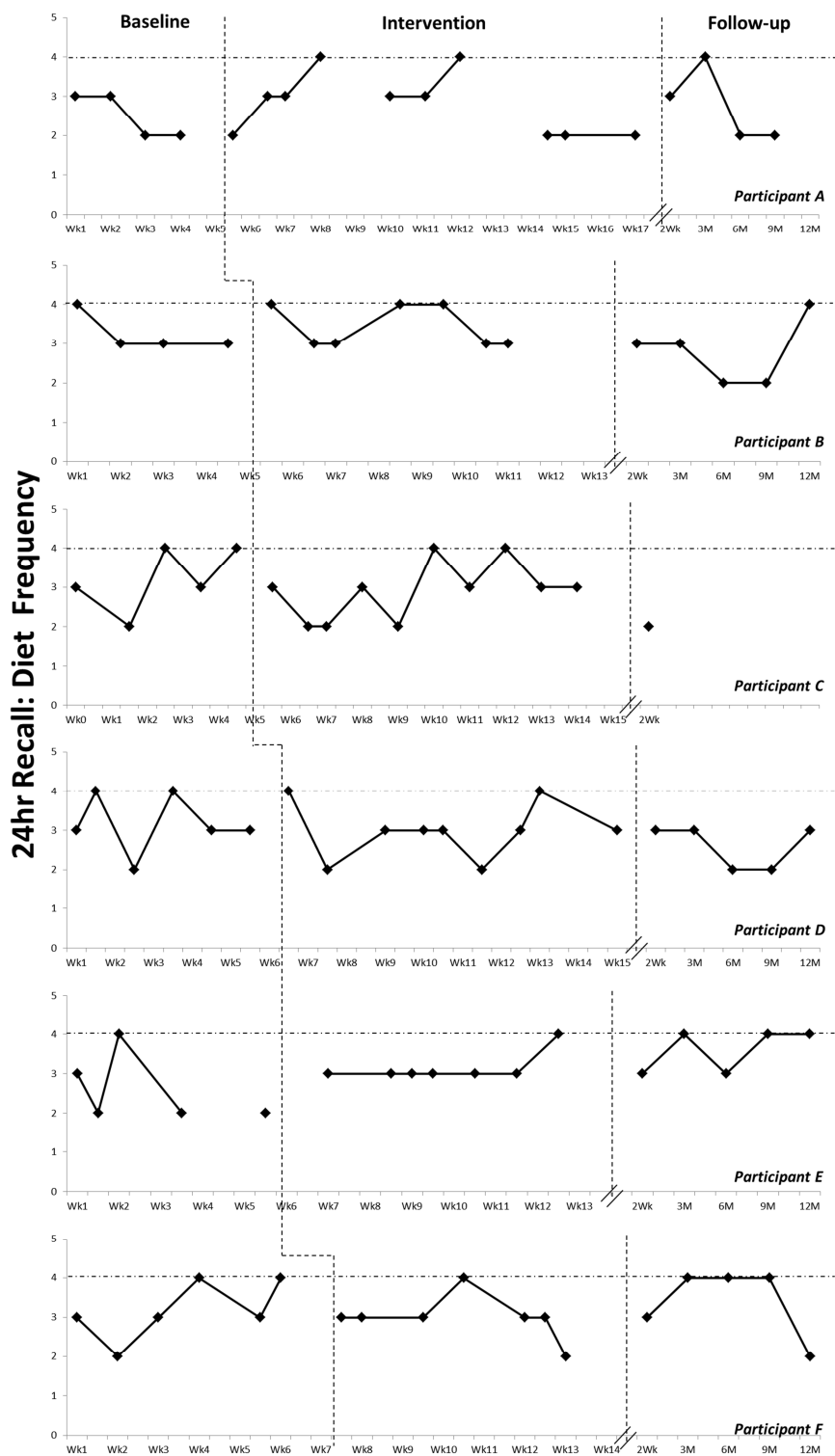


**Figure 4.7.** The PedsQL (a) Worry and (b) Communications mean scores at baseline and follow-up. \* = Clinically significant change (i.e.,  $|\text{reading}_2 - \text{reading}_1| \geq$  (a) 13.08, (b) 10.73), M = month, and Wk = week.

## **Secondary Outcome Measures: Adherence Recall Interview**

### **Diet frequency**

Results from the 24hr recall of diet frequency are depicted in Figure 4.8. The diet frequency was defined as the total number of meals (breakfast, lunch and dinner) plus a bedtime snack, with four counts viewed as an acceptable level.



**Figure 4.8.** The 24hr recall: Diet frequency.

Participant A had a stable baseline for the diet frequency counts, with all observations below the recommended level of four, and a downward trend towards the end of baseline. During the intervention diet frequency was similar to baseline, although there were two days where this reached the recommended level. At follow-up there was a similar pattern, with one day at the recommended level. The results suggest a small improvement during intervention, which was maintained at follow-up.

Participant B's baseline diet frequency was stable with one day at the recommended level. During intervention there were three days out of seven that reached the recommended level. During follow-up Participant B had a different pattern from that in baseline and intervention, with his diet frequency dropping to include two days in which the frequency was only two, although there was still one day at the recommended level. The results suggest an improvement during intervention but this was not maintained at follow-up.

Participant C mostly had a stable baseline, with an upward trend and two days out of five at the recommended level. During intervention this participant continued a similar pattern, but had lower counts during early intervention and then later in the intervention had two days at the recommended level. The follow-up data is only available at the 2-week mark and had a count of two, which is below the recommended level. The results suggest an improvement in the later part of the intervention which was not maintained during follow-up.

Participant D had a near stable baseline and counts mostly were closer to or at the recommended level. A similar pattern continued during the intervention but

during follow-up there appeared to be deterioration with no counts at the recommended level. The results suggest no improvement during intervention and follow-up.

Participant E's baseline diet frequency was mostly below the recommended level; however, during intervention they became more stable and closer to the recommended level. During follow-up there appears to have been further improvement, with over half of the diet frequency at the recommended level. The results suggest an improvement during intervention with further improvement during follow-up.

Participant F had a near stable baseline diet frequency mostly closer to or at the recommended level, with an upward trend towards the end of baseline. A similar pattern continued during the intervention period. During follow-up, however, all but one of the observations were at or close to the recommended level, which suggest an improvement in the diet frequency during follow-up.

In summary, four participants showed an improvement in diet frequency during the study. Participant E had a stable improvement in diet frequency during intervention, with further improvement at follow-up with more counts at the recommended level. Participant A had a slight improvement during intervention, which was maintained at follow-up. Participant F had an improvement during follow-up. Participant B had a slight improvement during intervention which was not maintained at follow-up. The other two participants (Participants C and D) had no improvement during intervention, and Participant C had a slight decline at the 2-week follow-up (the remaining follow-up data are missing).

## Frequency of SMOBG

Results from the 24hr recall of frequency of SMOBG are depicted in Figure 4.9. The SMOBG frequency was defined as the total number of blood glucose tests at the three meals and before bedtime, where an acceptable level is a total of four counts.

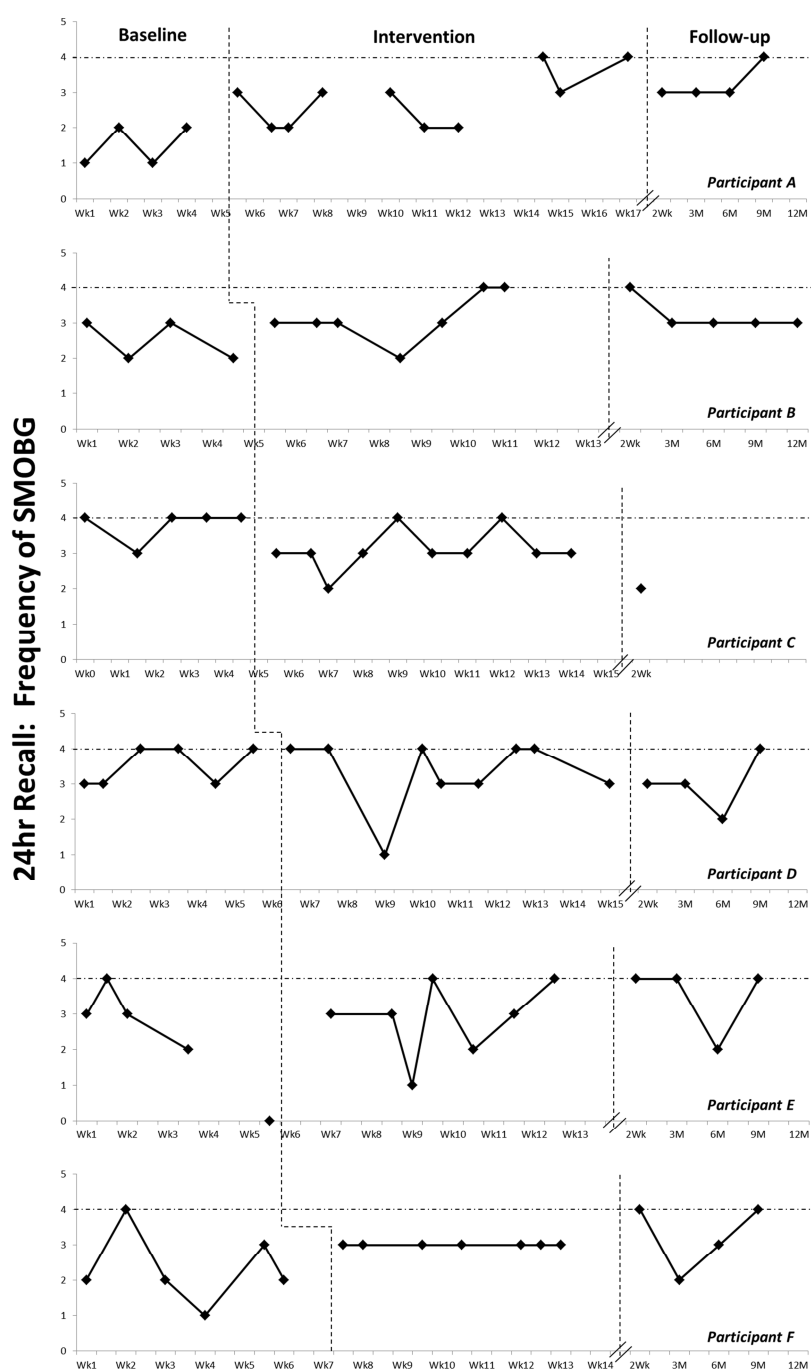


Figure 4.9. The 24hr recall: Frequency of SMOBG.

Participant A had a stable baseline for the frequency of SMOBG, with all observations below the recommended level of four. During the intervention the frequency of SMOBG increased with two counts at the recommended level and no counts below two. At follow-up the counts were mostly three with one count at the recommend level, which suggests a further improvement from baseline and intervention of not having counts less than three. The results suggest an improvement during intervention which was maintained at follow-up.

Participant B's baseline frequency of SMOBG was stable with all counts less than the recommended level. During intervention, however, two counts reached the recommended level and only one out of seven counts was less than three, which suggests an improvement from baseline. An increase in the frequency of SMOBG was maintained during follow-up with a slight improvement of not having any counts less than three.

Participant C had a stable baseline with four out of five counts at the recommended level. During intervention the frequency of SMOBG decreased, with only two points out of the ten at the recommended level. This suggests a slight deterioration during intervention. Follow-up data are only available at the 2-week follow-up point and was below the recommend level.

Participant D had a stable baseline with an equal number of counts at three and four. During the intervention there was a similar trend to the baseline scores, with five counts out of nine at the recommended level. At follow-up a similar pattern of being mostly close to the recommended level continued. The results suggest no improvement during intervention and follow-up.

Participant E's baseline had a downward trend, with one count at the recommended level and another at the end of baseline at zero. During intervention there were no counts at zero and two counts at the recommended level, which suggests a slight improvement from baseline. During follow-up the pattern suggests a further improvement, with three out of four observations at the recommended level.

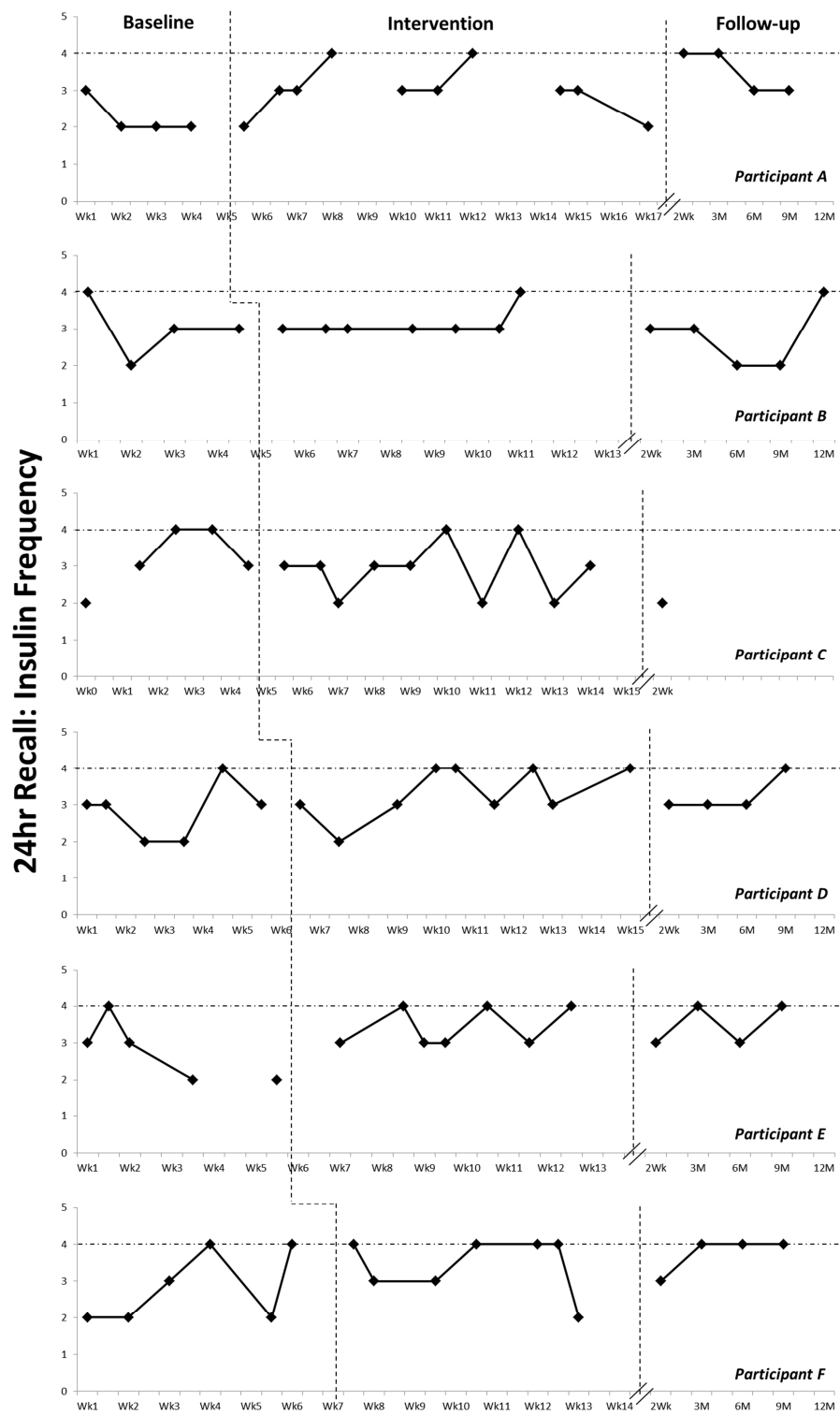
Participant F's baseline was variable, with mostly a frequency of SMOBG below the recommended level. During the intervention, however, the frequency of testing became more stable, with three tests per day for seven days. This pattern suggests a slight improvement, although during intervention the frequency of SMOBG was still not at the recommended level. During follow-up, the frequency of testing was variable again, although there were two counts at the recommended level. The results suggest a slight improvement in the frequency of SMOBG during intervention but the follow-up scores regressed to a similar pattern in baseline.

In summary, four participants had improvements in the frequency of SMOBG during the study. Participants A, B, and E had improvements during intervention that were maintained at follow-up. Participant F had a small improvement during intervention, this, however, was not maintained during follow-up. Participant C appeared to have a slight deterioration during intervention, but maintained values that were mostly close to the recommended level. Participant D had no improvement during intervention or follow-up.



### **Insulin frequency**

Results from the 24hr recall of insulin frequency are depicted in Figure 4.10. Insulin frequency was defined as the total number of insulin doses at the three meals and before bedtime, where an acceptable level is a total of four counts.



**Figure 4.10.** The 24hr recall: Insulin frequency.

Participant A's insulin frequency during baseline was stable and mostly below the recommended level. During the intervention two out of ten counts were at the recommended level and six out of the ten were close to that, suggesting an improvement from baseline, which appears to have been maintained during follow-up.

Participant B's baseline was variable and mostly below the recommended level, with only one out of four points at the acceptable level. A similar, but more stable pattern was observed during intervention, with all points at three, except one point at the recommended level, which suggests a small improvement from baseline. Follow-up showed a similar variable pattern. The results suggest a slight improvement during intervention, which was not maintained at follow-up.

Participant C during baseline had a variable pattern, with two of the five points at the recommended level. A similar pattern continued during intervention, with two counts out of 11 at the recommended level. During follow-up she only had one point at count two. The results suggest no improvement during intervention or at follow-up.

Participant D had a variable baseline with counts mostly below the recommended level. Although the data were still variable during intervention, there appears to have been an improvement, with four out of nine counts at the recommended level and only one observation less than three. During follow-up the observations were more stable, with no points less than three, and one observation at the recommended level. The results suggest an improvement during intervention that was maintained during follow-up.

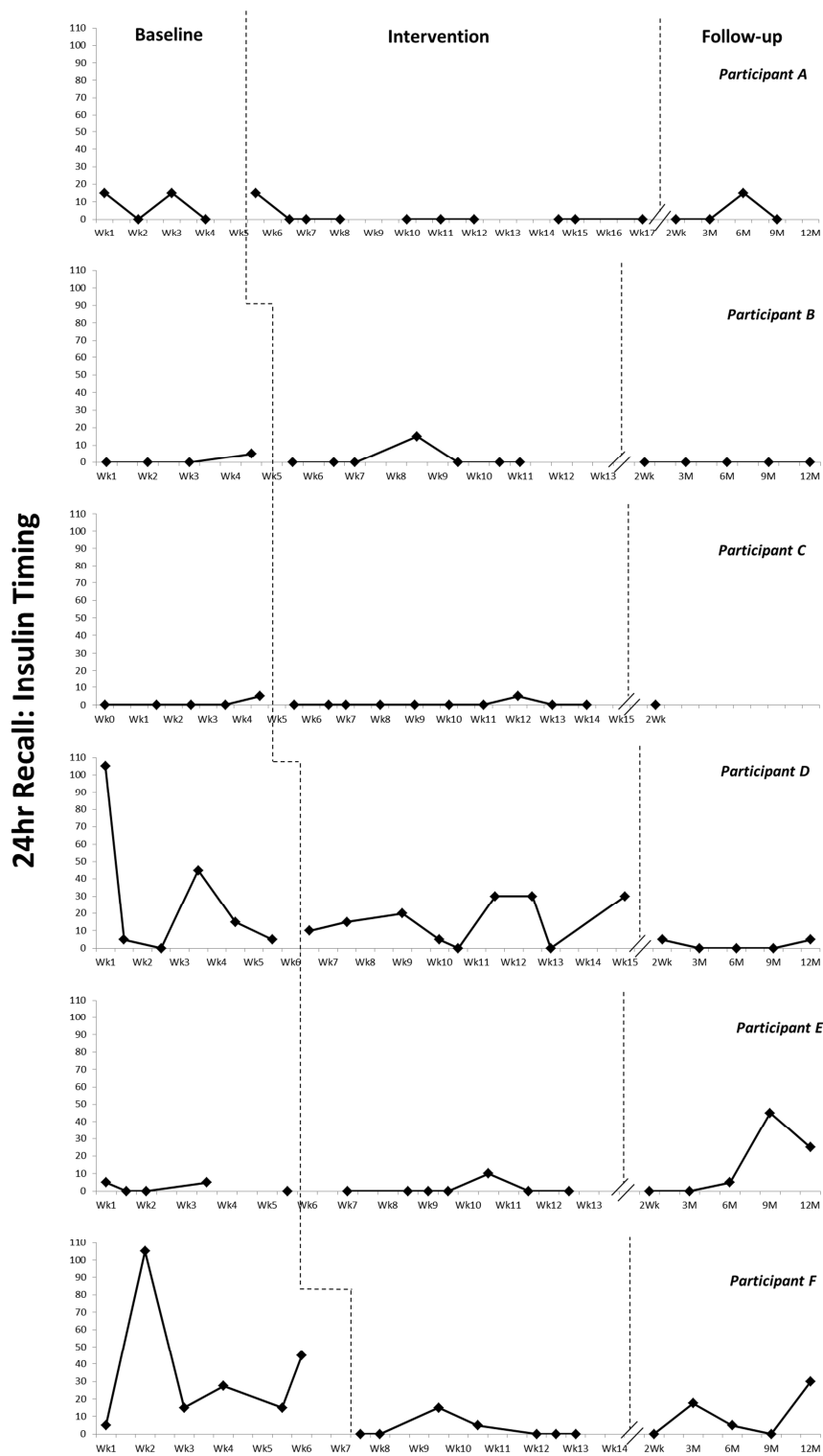
Participant E's frequency of insulin use during baseline appeared to show a downward trend, with two observations out of five at two and only one at the recommended level. There appeared to be an improvement during intervention with no counts less than three, and three of the seven counts at the recommended level. A similar pattern was observed during follow-up suggesting that the improvement was maintained.

Participant F's baseline was variable, with two points out of seven at the recommended level and three points at level two. An improved, more stable, pattern was observed during the intervention with four out of seven observations at the recommended level and only one observation with a count of two. There appears to have been further improvement at follow-up, with most of the observations at the recommended level and no counts below three.

In summary, four of the participants (Participants A, D, E, and F) had improvements in the insulin frequency during intervention, which was maintained during follow-up. The remaining two participants (Participants B and C) had no improvement during intervention or follow-up.

### **Insulin timing**

Results from the 24hr recall of insulin timing, measured in minutes, are depicted in Figure 4.11. Insulin timing was estimated by deducting the time between the insulin dose and meal time, which needed to be at most 15 minutes apart, and therefore 15 minutes was subtracted from the reported insulin timing. An average time was then calculated; zero minutes is considered to be the acceptable timing average.



**Figure 4.11.** The 24hr recall: Insulin timing (minutes).

Participant A had a pattern of alternating insulin timing points at baseline, with two out of four timings at the recommended level and another two exceeding that. He then had very stable insulin timing during intervention at zero level, with the exception of the beginning of the intervention. During follow-up he mostly maintained timings at level zero (three out of four). This suggests an improvement in insulin timing during intervention, which was maintained during follow-up.

Participant B's baseline was near stable, with three out four timings at the recommended level, and only the last baseline point sitting above that. A similar stable pattern was maintained during intervention, with six out of seven timings at the recommended level. An even more stable pattern was observed at follow-up, with all the timings at zero. The results suggest good adherence in baseline and intervention and an improvement during follow-up.

Participant C's baseline was near stable, with four out five timings at the recommended level, and with the last baseline point sitting above that. A similar stable pattern was maintained during intervention with nine timings out of ten at the recommended level. During follow-up a pattern could not be established because of missing follow-up points, but the observed follow-up point was at the recommended level. The results suggest good adherence in baseline and intervention, which was maintained at the follow-up.

Participant D during baseline had timings that were variable and considerably exceeded the recommended level, with only one timing out of six at the recommended level. A similar but less variable pattern was observed at intervention, which had lower levels of timings compared to the extreme timings at baseline. The

pattern improved and was more stable during follow-up, with most timings at or very close to the recommended level. The results suggest a slight improvement during intervention, with further improvement during follow-up.

Participant E had a stable baseline with all timings at or very close to the recommended level. A similar pattern was observed during intervention, with six out seven timings at the recommended level. During follow-up this pattern was maintained, apart from the 9-month and 12-month follow-up when the timings exceeded the recommended level. The results suggest no improvement during intervention and a slight deterioration during follow-up.

Participant F had a variable baseline, with most of values exceeding the acceptable level and had extreme values. During intervention, however, a drop in insulin timing was observed with five out of seven timings reaching the recommended level and no reported extreme values. During follow-up a similar, more stable pattern was observed, with two out five timings at the recommended level. The results suggest an improvement during intervention which was maintained at follow-up but with a slight regression to baseline.

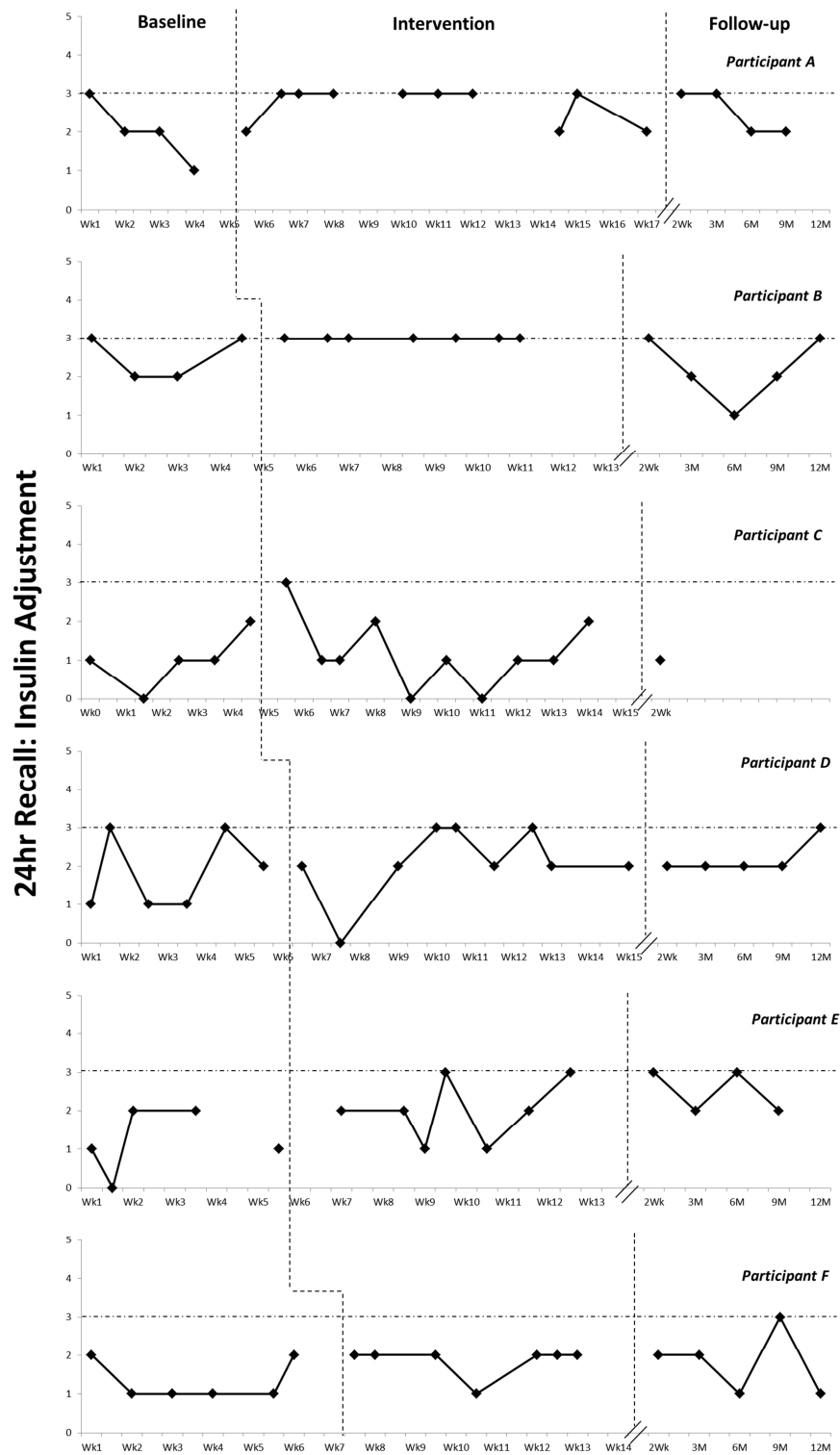
In summary, four participants showed an improvement in insulin timing during the study. Participant A had an improvement in insulin timing during intervention, which was maintained at follow-up. Participant B appeared to have had good adherence in insulin timing during baseline and intervention, which was further improved at follow-up. Participant D had a slight improvement during intervention, which was maintained with further improvement at follow-up. Participant F had an improvement during intervention which was maintained at follow-up but with a

slight regression to baseline. One of the remaining two participants, Participant C, had good adherence in baseline and intervention, which was maintained at the follow-up. Participants E had no improvement during intervention and a slight deterioration during follow-up.

### **Insulin Adjustment**

Results from the 24hr recall of insulin adjustment are presented in Figure 4.12. The insulin adjustment frequency referred to the number of times the correct amount of insulin was taken at three meals; the acceptable level was three, which indicated that at each meal time the participant took the correct amount of insulin, based on her or his blood glucose level and the number of carbohydrate units consumed.





**Figure 4.12.** The 24hr recall: Insulin adjustment.

Participant A had an insulin adjustment baseline which was trending down with most counts below the recommended level of three. During intervention, however, he had seven out of ten counts at the recommended level and no counts below three. A similar pattern was maintained at follow-up. The results suggest improvement during intervention that was maintained during follow-up.

Participant B during baseline had two out of four counts at the recommended level, and then during intervention had all counts at the recommended level, which suggests an improvement. During follow-up, however, the counts regressed to a similar pattern to baseline, with a count at level one. The results suggest although there was an improvement during intervention, it was not maintained during follow-up.

Participant C's insulin adjustment was variable and below the recommended level during baseline. A similar pattern continued during intervention, which suggests no improvement. At the follow-up there were not enough points to establish a pattern. The only point for which there was a reading was below the recommended level.

Participant D had variable baseline, with two counts out of six at the recommended level. A similar pattern continued during intervention, with an improvement from mid-intervention with no counts less two. The follow-up pattern was even more stable and with no counts below two. The results suggest a slight improvement during intervention and a further improvement during follow-up.

Participant E baseline counts were variable with all below the recommended level and none above two. During the intervention there appeared to be a slight

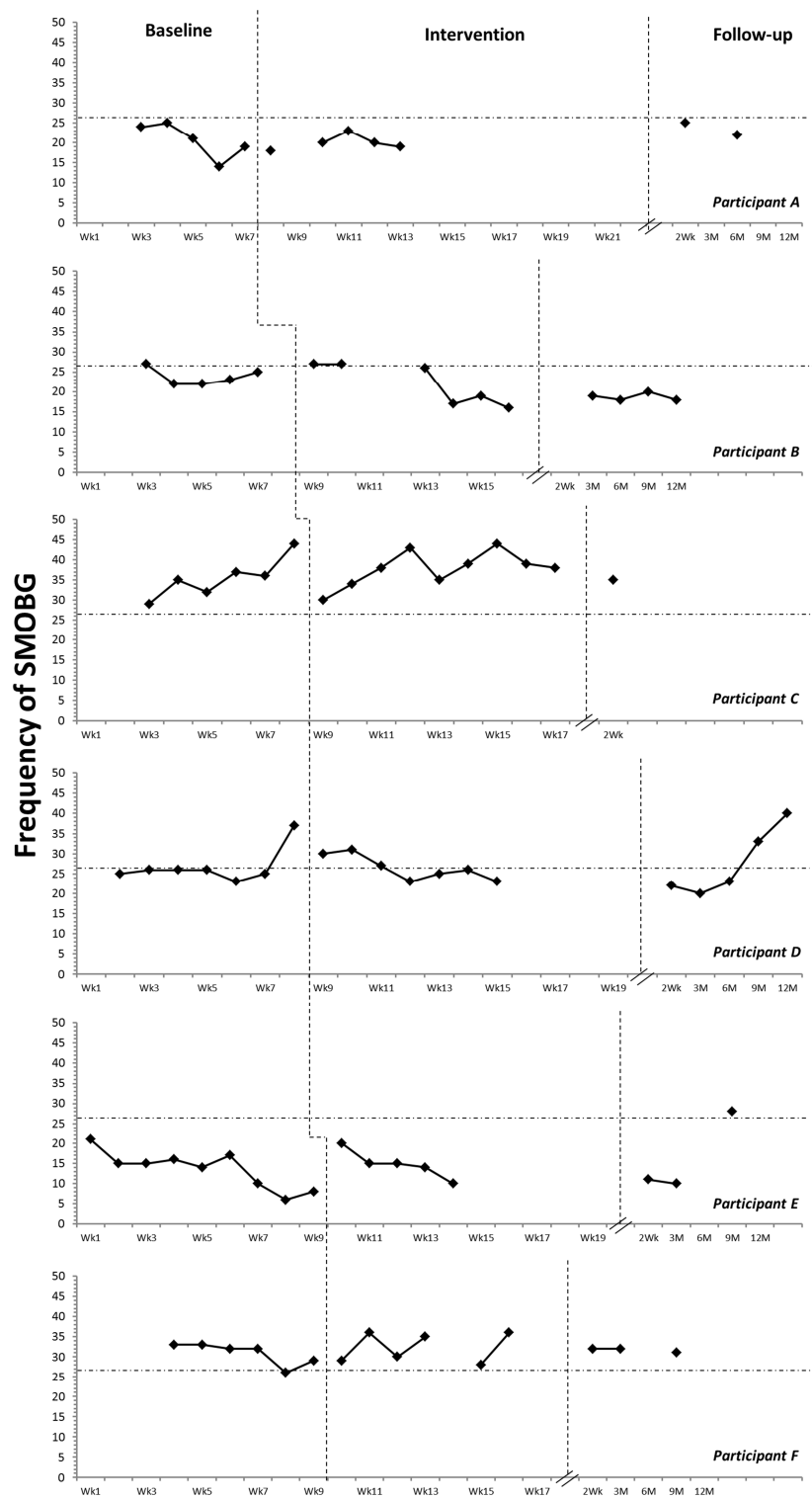
improvement, with two out of the seven counts at the recommended level and none of counts at level zero. There was further improvement at follow-up with a more stable pattern and no counts less than two.

Participant F baseline was fairly stable with mostly counts of one. An improved, fairly stable pattern was observed during intervention with six out of seven values just below the recommended level. During follow-up the pattern was more variable but, unlike baseline or intervention, there was one count at the recommended level. The results suggest an improvement during intervention and a possible further improvement during follow-up.

In summary, five out six participants had an improvement in their insulin adjustment frequency during the study. Participants D, E, and F had an improvement during intervention, and with a possible further improvement observed during follow-up. Participant A had an improvement during intervention that was maintained at follow-up. Participant B although had an improvement during intervention, but it was not maintained during follow-up. Participant C did not have an improvement during intervention or follow-up.

### **Frequency of SMOBG per week**

Results from the frequency of SMOBG per week are presented in Figure 4.13. The weekly SMOBG data (tabulated) were provided by participants from their blood glucose meters. A frequency of 28 was the minimum acceptable level of SMOBG per week.



**Figure 4.13.** Frequency of SMOBG per week.

Participant A's weekly frequency of SMOBG during baseline was variable and below the recommended level of 28, with three out of six weeks in the 20s range. A similar pattern was observed during intervention and follow-up, although data were missing for the later intervention and follow-up. The available data suggest no improvements to the frequency of SMOBG during intervention and follow-up.

Participant B's frequency of SMOBG at baseline was fairly stable but mostly below the recommended level. Whilst during early to mid-intervention there were three weeks in which the frequency was close to the recommended level, this however was not maintained during the latter part of the intervention. A similar pattern to the latter intervention period continued during follow-up, which suggests a slight decline from baseline in the frequency of SMOBG.

Participant C had similar patterns during baseline and intervention, with the 2-week data consistent with these patterns. The frequency of SMOBG always exceeded the recommended level, indicating a high frequency of SMOBG on a daily basis during baseline and intervention.

Participant D's frequency of SMOBG during baseline was close to the recommended level, with the exception of one week at the end of baseline which was above the recommended level. A similar pattern continued during intervention with a frequency of SMOBG that was close to or at the recommended level most weeks, and two weeks where this was exceeded. Again, a similar pattern appeared during follow-up, with the frequency of SMOBG exceeding the recommended level at the 9-month and 12-month follow-up, which suggests an improvement towards the end of the follow-up period.

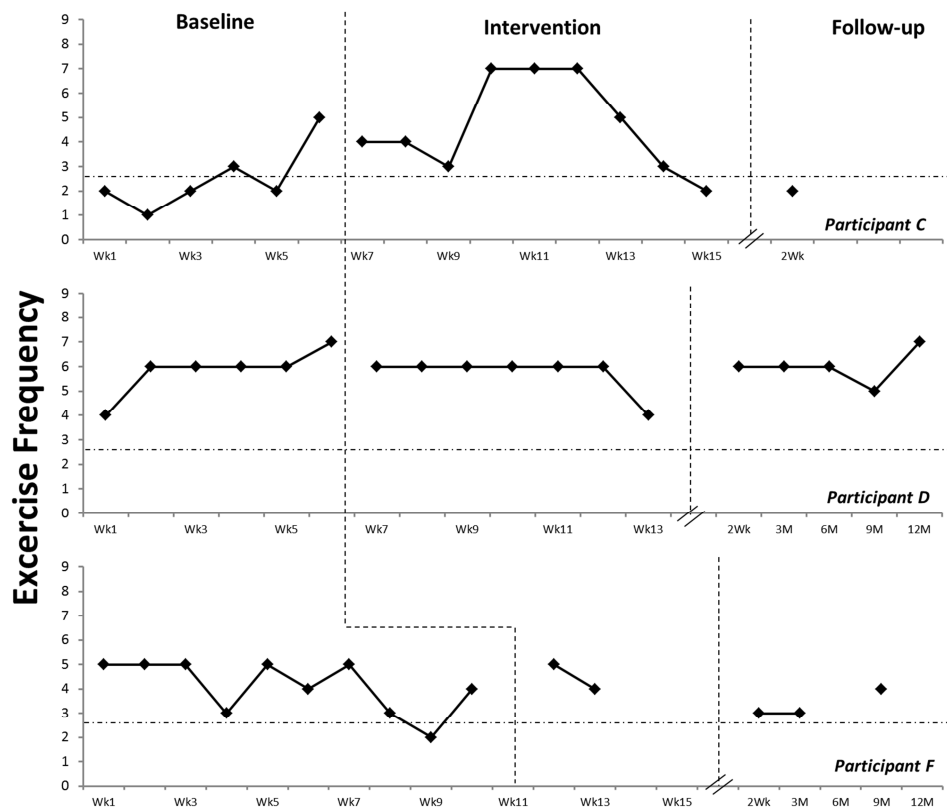
Participant E had a variable baseline, with no frequency of SMOBG at the recommended level, which was similar during intervention and follow-up. This suggests no change during intervention or follow-up, although there was one week during follow-up which the frequency of SMOBG reached the recommended level.

Participant F during baseline had a frequency of SMOBG that was all at or above the recommended level. During intervention there was an improvement, with the frequency of SMOBG exceeding the recommended level in all weeks, which was maintained during follow-up

In summary, two of the participants appeared to have had some improvement in the frequency of SMOBG. Participant F had a small improvement during intervention which was maintained during follow-up. Participants D and E had small improvements during follow-up. Participant C satisfied the minimum frequency of SMOBG recommendations during baseline, intervention, and the 2-week follow-up without any further changes. The remaining two participants had no improvements. Participant A had no change in the frequency of SMOBG during intervention and follow-up, whereas Participant B had a slight deterioration in the frequency of SMOBG during the latter part of the intervention and follow-up.

### **Physical Activity**

Results from the total physical activity per week are depicted in Figure 4.14; three participants (Participants A, B, and E) did not provide data on physical activity throughout baseline, intervention, or the follow-up period. A minimum of 20 minutes three times a week of physical activity was considered the minimum acceptable level.



**Figure 4.14.** The total physical activity per week: Exercise frequency.

Participant C's physical activity levels during baseline were variable, and mostly below the recommended number of three. During the intervention the pattern changed, with all but one week meeting or exceeding the recommended level, which suggests an improvement in the physical activity frequency during intervention. It was not possible to discern a pattern during follow-up because the only data available was for the 2-week follow-up point, and the earlier improvement was not maintained at that 2-week follow-up mark.

Participant D maintained similar patterns of activity during baseline, intervention, and follow-up. All of the readings exceeded the recommended level, with the participant exercising at least four times per week. The results suggest the participant satisfied the minimum physical activity recommendations throughout

baseline, intervention, and follow-up.

Participant F's physical activity during baseline was variable, ranging from two to five times per week, but mostly exceeded the recommended level. During intervention also the two available data points exceeded the recommended level but because further data during intervention is not available it is not possible to comment on any trends during intervention. Similarly, during follow-up all weeks at least met the recommended level, but missing data again limit the conclusions that can be drawn.

In summary, two of the participants had already met the minimum physical activity frequency recommendation. Participant C had an improvement in the physical activity frequency during intervention. Because of missing data it is unclear if this improvement were maintained during follow-up, although the improvement was not maintained at the 2-week follow-up.



## Summary

The main findings of the analysis are as follows. The HbA1c results were neither statistically equivalent nor different at baseline and during follow-up and hence resulted in statistical indeterminacy. Individual data indicated that only one participant (Participant D) had a clinically significant decrease in HbA1c post intervention that was maintained at the 9-month and 12-month follow-up, despite a clinically significant increase at the 6-month follow-up. Three participants (Participants B, D, and E) who had data at the 6-month follow-up had a trend of an increasing HbA1c, and then a drop in HbA1c in the subsequent follow-ups (9-month and 12-month).

Glycaemic Variability outcomes, from baseline to intervention, generally showed improvements in the ADRR and HBGI risk outcomes, suggesting an improved stability in blood glucose fluctuations and therefore a lower risk for extreme blood glucose levels. The LBGI categories were maintained in the low risk range but with varying scores, except for one participant (Participant D) who had a category change from low to moderate risk.

The majority of the psychosocial results showed significant improvements from baseline to follow-up in the group data. Improvements were observed in the following measures: PedsQL total score, diabetes symptoms, and worry, as well as BIPQ, and CIDS. These results suggest improved overall diabetes QoL, fewer problems associated with diabetes symptoms, fewer worries about diabetes complications, less perceived threatening views about the diabetes condition, and a higher level of self-efficacy. Clinically significant changes in individual data were

also observed for most of the study participants during the study (Tables 4.16-4.18).

Improvements in diabetes self-management behaviours (as measured by the recall interview) were observed for all participants during the study. Of the six participants, four participants showed an improvement in diet frequency, four participants had improvements in the frequency of SMOBG, four participants had improvements in the insulin frequency during intervention, four participants showed an improvement in insulin timing during the study, five participants had an improvement in the insulin adjustment frequency during the intervention or follow-up or both, two of the participants had some improvement in the (weekly) SMOBG frequency, and two out three participants had already met the minimum physical activity frequency recommendation. In addition, although all participants improved at least one adherence behaviour during intervention, which was then maintained at follow-up, all except one participant (Participant C who withdrew) made improvements on multiple behaviours (at least three) during intervention and/or follow-up.

## **Discussion**

The data analyses suggest that the MI intervention contributed to positive changes in the primary and secondary outcomes measures. Group data suggest that the MI intervention contributed to clinically significant improvements in psychosocial functioning, but the intervention's contribution to changes in HbA1c was indeterminant. Individual data also suggest the intervention contributed to improvements in GV, adherence behaviours, and psychosocial functioning for the majority of the participants. There was also a pattern in the individual data, suggesting improved HbA1c after the booster session.

The above major findings are discussed as follows: primary outcome measures, secondary outcome measures, summary of findings, limitations, and recommendations for future research.

### **Primary Measure: Blood Glucose**

#### **Glycated haemoglobin (HbA1c)**

The results of the statistical tests of the group data for HbA1c, from baseline to follow-up, were statistically indeterminate; that is, both the statistical equivalence and the statistical difference tests failed resulting in the statistical indeterminacy. This means that no conclusion can be withdrawn about the impact of the MI intervention on HbA1c for the group data. This result may be due to a lack of statistical power because of the small number of participants and the missing data, in that three out of seven participants having data missing.

The results of the clinically significant change using single-case experimental

design showed that only one participant had a clinically significant improvement. This improvement was observed from baseline to the 2-week follow-up and was maintained during the 9-month and 12-month follow-up, despite a clinically significant increase at the 6-month follow-up. Nevertheless, a conclusion about the efficacy of MI cannot be drawn from the one participant's improved HbA1c profile, a consistent pattern need to be observed across the other participants.

For participants with a complete data set there was a notable pattern of an increase at the 6-month follow-up in three of four participants. This increase was followed by a clinically significant decrease at the 9-month or 12-month follow-up, or at both, with the 12-month follow-up reading always lower than that at 9-month follow-up. The common peak at the 6-month follow-up could be attributed to a seasonal effect phenomenon of increased HbA1c during autumn and winter (Hill, Peters, Thompson, Matthews, & Hindmarsh, 2013; Mianowska et al., 2011; Nordfeldt & Ludvigsson, 2000).

The 9-month HbA1c reflected a period after the booster session. A reduction in HbA1c occurred despite a potentially expected increase due to the seasonal effect during winter. The observed changes in HbA1c may be attributed to the MI intervention and the booster session in particular. A meta-analysis by Hettema et al. (2005) stated that "if MI is offered as a stand-alone intervention, long-term effects may be enhanced by booster sessions" (p. 104). Future research could investigate the role of booster sessions in MI interventions for diabetes, which was also recommended in previous diabetes research (Britt, 2008).

There is evidence for the usefulness of booster sessions in other MI research.

For example, Chapman and Armitage (2009) found that adding a booster session improved the long-term impact of MI to increase fruit and vegetable intake beyond 6 months. Similarly, Longabaugh et al. (2001) found that the MI plus a booster at 12-month follow-up reduced alcohol related injuries by 30% in participants who presented at an emergency department with an injury and screened positive for heavy or harmful drinking, compared to those who received standard care.

An alternative explanation to the observed pattern of a decreased HbA1c after 6 months from the MI intervention is a *sleeper effect* (Miller & Rollnick, 2013). Intervention effects on outcome variables vary depending on what they measure and whether they are *slower-moving* outcome measures (Miller & Rollnick, 2013). An HbA1c reading represents the average blood glucose level over the previous 2 to 3 months, that is, there will be a delay until an effect on HbA1c can be observed. Furthermore, for an observed change in HbA1c there need to be behavioural changes (e.g., medication compliance, exercise, and dietary compliance), and the effect of these behaviours on HbA1c may not be immediate.

At the 12-month follow-up, the level of reduction in HbA1c (from the 6-month follow-up), was not only a clinically significant decrease, but also suggests that the decrease may also contribute to a reduction in the risk for microvascular and macrovascular diabetes complications. For example, a large scale study showed that a reduction of 1% (11 mmol/mol) for people with type 1 diabetes significantly reduced the risk for diabetes complications of retinopathy, nephropathy, neuropathy, and cardiovascular conditions (DCCT Research Group, 1993, 1996). Thus, the HbA1c reductions observed in the current research were sufficient to potentially translate to reductions in diabetes complications.

To summarise, the above suggests that the MI intervention contributed to changes in HbA1c, which was observed mostly post the booster session. A stronger conclusion about this effect, however, requires further investigation.

Previous research has found, after an MI intervention, statistically significant reductions in HbA1c based on group data analysis (Channon et al., 2003; Huws-Thomas, 2007), but the current study did not find statistically significant changes. The small number of participants may have contributed to not detecting any statistically significant changes in the group data. The detection of statistically significant changes on an averaged effect, however, does not necessarily equate to being clinically significant or meaningful (Jacobson & Truax, 1991; Sedgwick, 2014).

Clinically meaningful results were observed in the context of the single-case experimental design. Individual data analysis had the advantage of focusing on changes at an individual level and observing emergence of patterns across participants. The analysis in the current study involved clinical and statistical significance tests and accounted for biological variation in HbA1c; that is, accounted for inconsequential differences and detected meaningful changes. Individual data analysis and clinical significance have not previously been presented in research investigating the efficacy of MI for youth with poorly controlled diabetes.

### **Glycaemic variability**

The GV profiles showed improvements from baseline to the end of intervention for the majority of participants. The changes were observed in ADRR, LBGI, and HBGI. There was a reduction in ADRR scores for five of six participants,

with two changing risk categories from a higher to a lower risk level. This means that glycaemic excursions, compared to baseline, were relatively less severe towards the end of the intervention. It also suggests that participants who had a decrease in ADRR scores and risk category were at a substantially reduced risk for having extreme glycaemic excursions, and therefore potentially reduced their risk for short-term and long-term diabetes complications (Bode, 2008; Kovatchev et al., 2006).

Similarly, the HBGI score for the majority of participants decreased from baseline to end of intervention, indicating less frequent hyperglycaemia episodes. Furthermore, the HBGI risk category was downgraded for two of six participants, which means they became at a substantially lower risk of having extremely elevated blood glucose levels and therefore had lowered risks for severe complications. Persistent and untreated hyperglycaemia causes serious and life-threatening complications, such as diabetic ketoacidosis, nerve damage, kidney damage and heart disease (Donaghue et al., 2009).

All, but one, of the participants had a score in the low risk category for hypoglycaemia at baseline, which means that they were at a low risk of having low blood glucose levels. This is consistent with previous research, which suggests that individuals who are compliant to tight glycaemic control and those with lower average glucose levels are at greater risk for hypoglycaemia (DCCT Research Group, 1997; Fowler, 2008; Havlin & Cryer, 1988). This was unlikely for the participants in the current study because they all had poorly controlled diabetes. The LBGI score for two Participants (D and F) increased towards the end of the MI intervention; but only Participant D had an upgraded risk category from low to moderate. It was also noted that Participants D and F had a clinically significant drop in HbA1c measured at the

2-week follow-up, which appears to be consistent with this increased risk of hypoglycaemia, and highlights the difficulties in diabetes control whereby attempts to lower blood glucose and avoid the consequences of hyperglycaemia can increase the individual's risk of hypoglycaemia (DCCT Research Group, 1997; Fowler, 2008; Havlin & Cryer, 1988).

In summary, the results of the current research suggest that the MI intervention contributed to improvements in GV risk factors and improved blood glucose stability. There was some reduction in the severity of glycaemic excursions and risk for hyperglycaemia for the majority of participants towards the end of the intervention, with a minority achieving a change of risk category. The reduction of scores, even without a category change, is an indication for improved blood glucose stability and less frequent extreme glycaemic episodes.

Glycaemic Variability has been found to be associated with changes in Hb1Ac and the level of risk of complications (Krishna et al., 2013; Rohlfing, Hsiao-Mei, Little, England, & et al., 2002). It is, therefore, recommended that future studies on diabetes interventions include GV evaluations across the study period. For the current study there were insufficient SMOBG data to carry out GV evaluations during follow-up.

### **Secondary Outcome Measure: Psychosocial Functioning**

The group data suggest that the intervention contributed to significant improvements in psychosocial functioning in the youth, and positive changes were mostly maintained or improved further at follow-up. Improvements were observed in five out of eight psychosocial measures from baseline to follow-up. These were:



PedsQL total score, diabetes symptoms, worry, BIPQ, and CIDS. This means that youth at follow-up compared to baseline had improved overall diabetes QoL, with fewer problems associated with diabetes symptoms, fewer worries about diabetes complications, less threatening views about diabetes, and a higher level of self-efficacy in relation to diabetes management. The results are consistent with previous findings which have found positive effects of standalone MI interventions on psychosocial functioning (Channon et al., 2003; Huws-Thomas, 2007).

The individual data were consistent with the group data, generally showing improvements in scores over time. Reliable changes in scores, a measure of clinical significance, however, were mostly observed on the CIDS and PedsQL total scores. There were some reliable changes observed in the remaining measures, but none in BIPQ. This also suggests that although the group data showed statistically significant changes at follow-up, and the descriptive individual data displayed that, clinically reliable changes were not always observed, and any changes may have been due to chance variation.

A possible explanation for not observing clinically reliable changes in some questionnaires, including none in BIPQ, may be because of the estimated SEM and Cronbach alpha of these scales (i.e., questionnaire's reliability). The BIPQ Cronbach alpha was found to be 0.704 (see Chapter 3). This reliability affects the SEM value, and thus the spread of  $S_{diff}$ . A relatively low reliability means a high SEM and therefore a wide  $S_{diff}$ , which means the spread of distribution of score changes due to chance variation is wider than that when the reliability is high. In contrast, the CIDS and PedsQL-Total Cronbach alpha coefficients were both about 0.92, which represents excellent internal consistency and therefore  $S_{diff}$  was narrower and reliable

changes had a greater chance of being detected compared to that of BIPQ.

The above also suggest that the MI intervention contributed positively to clinically meaningful improvements in self-efficacy and the overall diabetes QoL. However, the MI effect on illness perceptions remains unclear, given that clinically reliable changes were not confirmed at an individual level, despite the detection of statistically significant improvement at a group level. Hence, future research is recommended to investigate this.

The degree of the potential impact of MI on the psychosocial measures in the group data from the current study ranged from medium to large. Data on the degree of impact of a standalone MI intervention for youth with type 1 diabetes have not been previously reported; however, meta-analyses of diabetes interventions have reported small to medium effect on diabetes outcomes, such as HbA1c and psychosocial outcomes (Hampson et al., 2000; Winkley et al., 2006). This suggests that MI may be effective, and potentially more beneficial, than other interventions for youth, given the moderate to large effects obtained in the current study. Future research is recommended to further investigate the effect of MI on psychosocial functioning.

### **Secondary Outcome Measure: Adherence to Diabetes Self-management**

The MI intervention contributed to improvements in diabetes adherence behaviours, with all participants showing an improvement in at least one adherence behaviour during intervention, which was maintained at follow-up. These results are consistent with a finding by Channon et al. (2003) that youth reported at least one change on adherence behaviours after their MI intervention.

In addition, five of the six participants (Participants A, B, D, F, and E) made improvements in multiple behaviours (at least three behaviours). Furthermore, the three participants (Participants A, B and F) who improved adherence to most of the 24hr adherence behaviours, including blood glucose and insulin components (i.e., SMOBG frequency, insulin frequency, insulin timing, and adjustment), also had a risk factor downgrade in the GV risk categories between baseline to intervention. Thus, improvement in adherence behaviours that relate to blood glucose monitoring and insulin may have had an impact on blood glucose fluctuations and lowered the risk for extreme values.

This finding is consistent with evidence that blood glucose monitoring and insulin are essential components in diabetes management and also in improving GV (Bode, 2008; LeRoith & Smith, 2005). Research recommends the use of SMOBG to evaluate GV and therefore make necessary adjustments to address extreme blood values and blood glucose instability (Bode, 2008). Research shows that lowering HbA1c combined with improving GV by means of SMOBG also reduces the risk for complications (Hinzmann, Schlaeger, & Tran, 2012).

Participants B and F also had changes in HbA1c from baseline to the 2-week follow-up, consistent with improvements in adherence behaviours and reduced risk for extreme blood glucose values from baseline to intervention. Participant A, on the other hand, had an increase in HbA1c, which was in an opposite direction to that expected. This is despite of improved adherence behaviours and GV. This result is considered an inconsistent finding.

The interpretations of these results however need to be cautiously approached

because of the limitations of the study (see following sections). This includes collecting adherence data only once a week, which may not have reflected the reality of adherence during other days of the week; more frequent adherence data would have potentially addressed this but it may have led to other problems in terms of participant compliance with the study procedure (e.g., being available for daily adherence recall interviews). In addition, the GV data for participant A was analysed based on a fewer number than that known to produce optimal results (see Method section), which may have influenced the results, but even so the analysis was still considered reliable. The above result also implies that there may have been other factors that had an impact on HbA1c. Research shows factors such as iron deficiency, B<sub>12</sub> deficiency, excessive alcohol, excessive drugs (e.g., aspirin), depressive mood, viruses, and hormones contribute to an elevation in HbA1c (Aronoff, Berkowitz, Shreiner, & Want, 2004; Hanas, 2007; Hinzmann et al., 2012; NGSP, 2015; Nitin, 2010; Polgreen, Putz, & Stapleton, 2003; Van Tilburg et al., 2001). This suggests that HbA1c is influenced by a multitude of factors including physiological, psychological, and behavioural factors, and not merely one or the other. This also means that although individuals with diabetes could be completely adhering to medication and self-management recommendations, yet, physiological and other factors may interfere and have an impact on the HbA1c results.

In summary, the MI intervention appeared to have contributed to increased adherence to diabetes self-management behaviours, with most participants improving multiple adherence behaviours. However, these findings need to be treated with caution. Although the current adherence measure had the advantage that it evaluated changes in adherence behaviours based on a 24hr recall memory and blood glucose

meter weekly data (collected during non-concurrent baselines), it also had limitations. The measured 24hr frequencies provided a snapshot of the week, and a time point in each follow-up. Because these are only snapshots the results may not represent accurately the entire period. In addition, the 24hr recall is a self-report, which is less reliable than, for example, the blood glucose meter data or clinical measures (e.g., HbA1c). These limitations may have created some inconsistencies in findings. For example, two of the four participants who had improvements on the 24hr recall SMOBG frequency, did not show an improvement on the weekly SMOBG. This suggests that evaluating only one instance in a week may not always estimate the actual level of adherence or changes in that.

There is a general recognition of the difficulty of assessing self-management behaviours for clinical trials and finding a reliable and accurate representation of this (Budde, 2009; McNabb, 1997). There are many factors that contribute to this, which are mostly attributable to the complexity of the diabetes regime. Diabetes management may differ considerably amongst individuals with diabetes, with differing treatment plans, lifestyle adjustments, and co-existing conditions and morbidities. Hence, the generic guidelines may not be always applicable and a one-size-fits-all diabetes management may not simply exist. Therefore a standard adherence measure may not accurately represent adherence amongst all research participants. It could also fail to capture their true level of adherence when compared to others using the same measure.

Although a standardised measure, such as the 24hr adherence recall interview, may not match the diabetes self-management regime of all participants in a research study, it is still possible to observe patterns of change over time for each

participant, who serves as their own control as is the situation in single-case experimental design. In other words, a general adherence measure may be useful for monitoring changes in diabetes self-management behaviours within individuals.

It is recommended that future research collects adherence data from 24hr recalls more than once a week to increase confidence of patterns and changes. It is also recommended that future studies, with a large number of participants, also evaluate changes in adherence measures using statistical and clinical procedures rather than only by visual analysis. This, however, may require controlling for potential confounding factors from the differing individual adherence amongst participants.

## **Summary and Conclusion**

The MI intervention in the current study had a positive effect on primary and secondary outcome measures. Changes were observed in multiple variables across many participants. The overall findings were consistent with previous research on MI and diabetes and health behaviour change more generally (Channon et al., 2003; Christie & Channon, 2014; Gayes & Steele, 2014; Huws-Thomas, 2007).

The current study had the strength of using single-case experimental design with non-concurrent multiple baseline and person replication, which enhanced internal and external validity. The current study allowed comparisons both within-participants and between-participants, during and after intervention, and with each participant serving as their own control, which enhanced internal validity. In addition, replication of the effects of the MI intervention across participants and the use of a range of different and intensive assessments of dependent variables (i.e.,

behavioural, psychosocial, and clinical outcomes) enhanced the external validity of the results. Moreover, MI was delivered as a standalone intervention. The treatment fidelity was independently reviewed and confirmed that the MI was provided with a high level of skill. The study used both statistical and clinical significance analyses and accounted for potentially inconsequential differences (e.g., by using MCID, and CV). That is, the differences were clinically and statistically significant and reliable, and not because of chance variation, biological variation, or analytical biases. The present study, therefore, presented evidence for clinically meaningful results.

The study did, however, have weaknesses and limitations, and therefore, the results should be treated with caution. The limitations include a lack of statistical power, which may have led to not detecting statistically significant difference or equivalence, and therefore giving a result of indeterminacy for some measures. The study had a relatively small sample size and some data were missing. Furthermore, participants were all recruited from the same service, hence limiting the generalisability of results. Another weakness is related to self-report measures (e.g., 24hr recall data), which are relatively less reliable than objective measures (e.g., SMOBG meter readings and HbA1c). Nonetheless, the incorporation of a broad range of measures in the current study and observing changes across several measures provides more confidence in the treatment effect on the dependent variables. Finally, the adherence measure was solely visually analysed, which constituted a limitation in interpreting data and therefore findings are to be treated with caution.

To conclude, the current study provided evidence for the efficacy of MI for

youth with poorly controlled type 1 diabetes. Although the findings from this study are promising, further investigations are required to confirm and generalise results. At present, there are only three studies (including the current research) that have investigated the efficacy of MI as a standalone intervention for youth with type 1 diabetes. This shows that the MI research in the context of diabetes interventions for youth is still developing.

It is recommended that future research addresses the limitations in the current study to examine the MI efficacy for youth with diabetes in greater depth and to confirm the current study findings. This could include recruiting participants from multiple centers, and possibly extend it to a national or international level to boost recruitment and enhance internal and external validities. In addition, the clinical utility of MI could be investigated. Health professionals trained in MI could be involved in future trials of an MI intervention for youth with type 1 diabetes. This would clarify the practicality of delivering MI in the context a real world setting and achieving positive changes.



# Chapter 5

## *Conclusions and recommendations*

## **CHAPTER 5: CONCLUSIONS AND RECOMMENDATIONS**

### **Overview of the Thesis and Key Findings**

The management of type 1 diabetes is challenging and is influenced by developmental factors including physiological and psychological changes. This is particularly the case during adolescence when diabetes control often deteriorates (Borus & Laffel, 2010; Hamilton & Daneman, 2002; Pinhas-Hamiel et al., 2014). Additional health costs stem from long-term complications associated with poorly controlled type 1 diabetes, such as kidney failure and nerve damage (International Diabetes Federation, 2013). The burden on the health system may become greater if these long-term complications arise at an early age (Zhuo et al., 2014). It is therefore important for healthcare planning to study trends in diabetes in specific populations, and in particular for the youth population for whom diabetes management can pose significant challenges. Poorly controlled diabetes is common among the majority of youth with type 1 diabetes, and there is an urgent need to change this to minimise the risk of negative long-term consequences (Laffel et al., 2014).

This thesis has presented three studies, with the first two describing and studying specific characteristics of the target population. The third study evaluated an intervention for youth with type 1 diabetes. The intervention is one that has shown some promise in previous research, although results have been mixed and there were also methodological problems that limited the conclusions which could be drawn.

The first study in this thesis was an audit that provided up-to-date information on epidemiological characteristics and clinical outcomes (i.e., diabetes control) for the youth population with type 1 diabetes residing in the Canterbury region in New

Zealand. Data were collected from CDHB records of youth (15-24 year olds) with type 1 diabetes, with an anchor date that is seven years from a previous audit that was conducted in the region in 2003 (Wu et al., 2005). The prevalence of youth with type 1 diabetes was estimated in 2003 and 2010. The change in prevalence was then evaluated over time by using the ASPR (2010 being a reference year). This procedure accounted for any differences in the makeup of the population in the different years, and therefore gave a reliable estimate for the change in prevalence from 2003 to 2010. Changes in diabetes control at a population level in a subgroup of CDHB youth with type 1 diabetes (aged 15-20 years old) were also assessed over time from 2001 to 2010.

Key findings from the 2010 audit for the 248 youth with type 1 diabetes, who were identified in the CDHB catchment area in 2010, follow. The majority (91.5%;  $n = 227$ ) were European New Zealanders. The age-standardised prevalence of youth with type 1 diabetes (European New Zealanders) increased from 2003 to 2010 by 45 per 100,000. The ASPR was 1.19 (95% CI: 0.910 to 1.429). The majority (93.2%;  $n = 229$ ) of youth with type 1 diabetes had HbA1c levels that exceeded the recommended range for healthy diabetes control (i.e., less than 55 mmol/mol). The average HbA1c was 82 mmol/mol, which is classified as poor diabetes control. Diabetes control had not improved at a population level, when comparing data from 2010 with that in 2001.

The second study was a cross-sectional study that investigated the relationship between glycaemic control and key psychosocial characteristics: illness beliefs, self-efficacy, and QoL in youth with type 1 diabetes within the CDHB

catchment area. Youth identified in the audit study, who had a recent HbA1c reading, and whose type 1 diabetes was established, were recruited to take part in the psychosocial evaluation study. Psychosocial factors play an important role in influencing diabetes self-management and diabetes control (Delamater et al., 2014; Hagger & Orbell, 2003; Kovacs et al., 1997; Wysocki et al., 1992). Although there has been extensive research to explore a number of influencing factors, there are still gaps in knowledge particularly for the youth developmental stage, such as the role of certain psychosocial factors in predicting HbA1c levels. The current study addressed some of the gaps in knowledge in areas, such as investigating the individual and combined roles of illness perceptions, self-efficacy, and QoL in predicting glycaemic control. The examination of the combined and individual contributions can inform diabetes care systems, in particular interventions that target those with poor diabetes control. In New Zealand, the present study was the first to examine a combination of these key psychosocial factors in relation to diabetes control in youth (15-24 year olds) with type 1 diabetes. Nor has any previous study investigated any of these psychosocial factors with youth in Canterbury.

Key findings from the psychosocial evaluation of the 56 youth with type 1 diabetes (response rate was 23%), who agreed to participate in the cross-sectional study of this thesis follow. The mean HbA1c in this study was 77 mmol/mol ( $SD = 26.0$  mmol/mol), which is above the recommended level and in the suboptimal diabetes control range. The majority of youth (66.1%) had unsatisfactory levels of HbA1c, with more than half of those individuals (35.7%) falling in the poor and very poor HbA1c range. Only 5.8% were in the excellent diabetes control range. The regression analyses showed that: first, significant predictors of HbA1c were age,

illness perception and worry, which explained 36.9% of variation in HbA1c. Higher age predicted lower HbA1c, higher scores on the BIPQ predicted higher HbA1c, and more frequent worry about diabetes complications predicted lower HbA1c. Second, two of the BIPQ subscales were found to significantly contribute to HbA1c: *concern* and *personal control*, contributing respectively 3.5% and 10.1% to the variance of HbA1c. Higher perceived personal control was associated with lower HbA1c levels, and more perceived concern was associated with poorer HbA1c outcome. And third, a further exploration of the worry scale revealed that worrying about *going low* was a significant term that contributed 13.7% to explaining HbA1c. This result suggested that more worries about diabetes complications (specifically worrying about *going low*) were associated with better diabetes control.

The third study in this thesis investigated the efficacy of MI as an intervention for youth (16-24 years old) with poorly controlled type 1 diabetes (HbA1c > 64 mmol/mol). The study evaluated whether MI contributed to improved diabetes self-management, such as increased SMOBG and insulin adjustment, as well as clinical improvement in the glycaemic control, by using clinical, behavioural, and psychosocial measures. These measures comprised HbA1c, GV, frequency of SMOBG, adherence to diabetes self-management behaviours (e.g., insulin medication, timing and adjustment), and psychosocial questionnaires (BIPQ, CIDS, and PedsQL3.2). In addition, the fidelity of the MI intervention was evaluated using the MITI 3.1.1 coding system.

This study contributes to current knowledge and bridges some of the gaps in examining the efficacy of MI for youth with diabetes. It also addresses some of the

limitations in previous research so that the efficacy of MI for youth with poorly controlled type 1 diabetes can be more clearly evaluated. The research included evaluating the effect of a standalone MI intervention and provided evidence that the MI was delivered with high fidelity using the MITI 3.1.1. The study presents clinically meaningful results in the context of the single-case experimental design, which has not been presented previously in research that investigates the efficacy of MI for youth with poorly controlled diabetes. The current study is the first to explore and to quantify the degree of the impact (measured by effect size) of a standalone MI intervention on the psychosocial measures in youth with poorly controlled type 1 diabetes. The current study is also the first to include youth from the emerging adults developmental stage (i.e., 18-24 years), which is a vulnerable phase and this age group has not been the target for an MI intervention in previous diabetes studies.

The results of this thesis suggest that the standalone MI intervention had a positive impact on multiple diabetes outcomes across several participants; these are summarised below.

Individual data indicated a pattern across three of the six participants that suggest an improvement in HbA1c following the booster session at the 6-month follow-up, with improvements in HbA1c observed at 9-month and 12-month follow-up. Although the HbA1c group results were neither statistically equivalent nor different at baseline and during follow-up, with a consequential result of statistical indeterminacy, the result may be attributed to lack of statistical power.

Glycaemic Variability outcomes, from baseline to intervention, showed improvements in the ADRR and HBGI risk outcomes, which suggests improved

stability in blood glucose fluctuations as well as a lower risk for extreme blood glucose levels. Furthermore, the LBGI categories were maintained in the low risk range for all participants except for one (Participant D), whose LBGI moved from low to moderate risk. This participant also had reductions in HbA1c, and therefore may have achieved tighter control and consequently was at an increased risk of hypoglycaemia as has been suggested in previous research (DCCT Research Group, 1997; Fowler, 2008; Havlin & Cryer, 1988).

The majority of the psychosocial results showed significant improvements, with a medium to large effect from baseline to follow-up in the group data. Improvements were observed in the following measures: PedsQL total score, diabetes symptoms, worry, BIPQ, and CIDS. The results suggest that the participants had improved overall diabetes QoL, fewer problems associated with diabetes symptoms, fewer worries about diabetes complications, fewer perceived threatening views about the diabetes condition, and a higher level of self-efficacy. Clinically significant changes in individual data were also observed for most of the study participants during the study, primarily in the PedsQL total score and CIDS, and these results were maintained or further improved at follow-up.

Finally, improvements in diabetes self-management behaviours, as measured by the 24hr recall interview, were observed across multiple behaviours for several participants during the study. Five of the six participants made improvements on multiple behaviours (at least three) during the study. This suggests that participants performed adherence behaviours more frequently, with some reaching or exceeding the minimum acceptable level.

## **Weaknesses and Strengths of the Current Research**

The following presents a summary of the key weaknesses and strengths in this thesis, which have already been discussed in each of the respective chapters: audit, psychosocial evaluation, and MI intervention.

### **Audit**

In the audit study, discussed in Chapter 2, a complete number of cases of youth (15-24 year old) with type 1 diabetes within the CDHB catchment area may not have been identified. That is, there may be entries missing, which may have contributed to underestimating the prevalence. Capture-recapture was applied in the present study using the previous study records (Wu et al., 2005), but potentially missing entries could have been cross-checked using an additional capture-recapture method. This, for example, might have included setting a search date of two to three years back for checking hospital records instead of only one year back from the anchor date of November 2010. It is expected that youth with diabetes are examined medically at least once a year. It is possible that records may have been missed if they did not attend their annual check-up in 2010, or had not been admitted to the hospital during that period. More entries may have been captured, if the search period was extended to, for example, two years back from the anchor date.

Although the limitation discussed above may have resulted in missing entries and therefore the prevalence in 2010 may have been underestimated, the number of missing entries is believed to have been minimised. This is because multiple sources were thoroughly checked for youth entries, including the inpatient and outpatient hospital discharges and youth databases. The study had the strength of performing a



rigorous and systematic search by means of using medical codes, date of births, cross checking different sources in the CDHB hospital and diabetes centre databases, and accessing physical records and NHIs. In addition, cross checking records against Wu et al.'s data (2005) increased confidence of minimising missing entries. Furthermore, the study had the strength of retrieving missing data-point entries by searching the physical files held at the CDHB Diabetes Centre based on the NHI, and contacting the individual youth's GP.

The study had the strength of using a set of reliable procedures for evaluating changes in prevalence over time from 2003 to 2010. The study ensured compatible datasets (e.g., total and age strata population) for comparing 2003 and 2010. The study used the same data source and accounted for the difference in the classification of ethnicity in different census years. The study also had the strength that it controlled for a potential confounder from the different makeup of subgroups when comparing prevalences from two populations. This was ensured by calculating an age-standardised prevalence and ASPR rather than just using crude prevalences for evaluating change in prevalence over time.

### **Psychosocial Evaluation**

In the psychosocial evaluation study, discussed in Chapter 3, limitations included the response rate (and sample size) of the completed questionnaires, as well as the homogeneity of the sample (i.e., youth from one region who attended the same health institute). The total population of CDHB youth with type 1 diabetes was 248 and it was unlikely that a large sample size would be obtained. The research faced the challenges posed by the effects of the 2010-2011 Canterbury earthquakes. One

consequence of the earthquakes is that many people were forced to move, and as a result 26 letters were returned as *invalid addresses* or *return to sender* and this would have contributed to the relatively small sample size. The sample size also seemed to play a role in limiting ability of the statistical models to explain extremely elevated HbA1c levels that are above 138 mmol/mol. Four HbA1c values ( $\geq 138$  mmol/mol) were considered influential outliers and were therefore excluded from the analysis. A larger sample size (with extreme HbA1c values) might overcome this limitation. The above suggests that the relatively small sample size and only involving youth from one city limits the generalisability of the results.

Despite the above limitations, the study had the strength of performing reliable analyses and detecting significant associations at an inferential level, rather than simply a descriptive level. The study involved pre-analysis evaluations, a cycle of validations, and controlled for confounding factors in the confirmatory analysis, namely: the questionnaires demonstrated valid reliability and therefore analysis was carried out with confidence, multicollinearity was minimised, and influential outliers were examined and then removed. The confirmatory analysis was then carried out using systematic procedures with further evaluation cycles (e.g. residual plots and regression diagnostics). The study also had the strength of explaining the variation in HbA1c in relation to the psychosocial characteristics of youth with type 1 diabetes, whilst meeting requirements for the selected statistical analysis tests. For these reasons it can be said that this study presented reliable evidence for the predictability of HbA1c from certain key psychosocial factors (e.g., illness perception and personal control).

## **MI Intervention**

In the MI intervention study, discussed in Chapter 4, limitations included lack of statistical power to detect statistically significant difference or equivalence, which therefore results in indeterminacy. The study had a relatively small sample size and some data were missing. Another weakness is related to self-report measures that were used (e.g., 24hr recall data), which are relatively less reliable than objective measures (e.g., SMOBG meter readings and HbA1c). Nonetheless, the incorporation of a broad range of measures in the study and observing changes across several of the measures gives greater confidence of the treatment effect on the dependent variables. The adherence measure was solely visually analysed, which constituted a limitation for the interpretation of data and therefore findings are to be treated with caution.

Despite the limiting factors outlined the study had a number of strengths. It used a single-case experimental design with non-concurrent multiple baseline and person replication, which enhanced internal and external validity. The current study compared within- and between-participants, both during and after intervention, with each participant serving as their own control, which enhanced internal validity. In addition, replication of the effects (i.e., the MI intervention) across participants and using different and intensive assessments of dependent variables (i.e., behavioural, psychosocial, and clinical outcomes) enhanced the external validity of the results. Moreover, MI was delivered as a standalone intervention and the analyses were specific to the MI effect. Treatment fidelity was independently reviewed, and verified, and the measures met or exceeded MI proficiency thresholds. Finally, the study used both statistical and clinical significance analyses and accounted for potentially inconsequential differences (e.g., by using MCID, and CV). That is, the

differences were clinically and statistically significant and reliable and not due to chance variation, biological variation, or analytical biases. The present study, therefore, presented evidence for clinically meaningful results.

## **Conclusions**

Diabetes is a global epidemic with a trend of increasing prevalence as shown in international and national research (International Diabetes Federation, 2013; Wild et al., 2004). The Canterbury region, in New Zealand, is not an exception and has had an increase from 2003 to 2010 in the prevalence of adolescents and young adults with type 1 diabetes as the results in the current thesis demonstrate. This suggests an increased demand on health resources, and for the healthcare system to consider how best to meet the needs of this increased demand. This thesis found that the level of diabetes control, at a population level in 2010, was in the poor glycaemic control range and that this has remained unchanged since 2001. This implies that poorly controlled diabetes has been the norm in this age group and indicates that there is an urgent need for more effective interventions that target this particular population.

It is recommended that health services review the current approach to youth with type 1 diabetes with the view to establishing more effective interventions, and specifically interventions focussed at youth with the poorest diabetes control. Furthermore, it is recommended that the key psychosocial factors that have been found to influence diabetes control in this age group be considered in the planning for future services to enhance their effectiveness. Key psychosocial factors that should be considered include self-efficacy, illness perceptions, perceived personal control over diabetes, coping and emotional adjustment, and QoL related factors such

as worry. Ongoing audits are also recommended to provide further up-to-date information about prevalence and diabetes control in Canterbury over time.

The current thesis found that diabetes control in youth with type 1 diabetes was influenced by factors, including diabetes illness perception, perceived personal control, diabetes-related concern, and worry about complications. The results were generally consistent with previous research in finding that these factors contribute to predicting HbA1c, and confirmed the expected direction of prediction (e.g., Griva et al., 2000; Pereira et al., 2011). Nonetheless, the *worry* finding deviated from what seems expected and there has been a lack of research investigating this in relation to predicting HbA1c. The overall results suggested youth who were worried about complications also had better diabetes control. However, this has to be managed carefully because having stronger beliefs about diabetes as a threatening condition may negatively influence diabetes control. Hence, the current thesis findings present a new understanding of the importance of balancing worries about diabetes complications and perceptions on diabetes as a threatening condition. This relationship has potential clinical implications, and therefore, it is recommended that this be researched further.

Further research is recommended to test and confirm if these findings can be generalised. It is also recommended that future research address the limitations identified in the current research, such as statistical power. This could be achieved by extending the research to other catchment areas in the South Island, or New Zealand as a whole. A multi-centre study conducted on a national level is suggested as preferable to facilitate a higher response rate. In addition, future research could investigate influential factors (e.g., HbA1c and worry), using mediational and direct

relationship models in a longitudinal study. This could facilitate establishing the causal relationships and to clarify the extent of effect amongst the process variables, including direct and mediational relationships (e.g., frequency of extreme glycaemic episodes as a lateral variable).

The MI intervention was successful in improving some diabetes outcomes – clinical, psychosocial, and behavioural changes were observed. Statistically and clinically significant positive changes were found across multiple variables. Improvements in GV, adherence, and psychosocial factors were observed during the study, with improvements in the latter two (which had follow-up data), being maintained or further improved during the follow-up period. Improvements in HbA1c were observed but with a delayed effect – there was a pattern of reduction post the 6-month follow-up. This may be explained by a potential role of a booster session or a sleeper effect. It is recommended that the role of booster session(s) be investigated in future research. Furthermore, it is recommended to evaluate the effect of MI beyond 12 months, for example, at 18-month and 24-month follow-up points. Research shows that long-term effects of psychosocial and behavioural interventions may not be sustained beyond 12 months (Harvey, 2015). This also suggests the potential need for adding a booster session during that period.

Furthermore, the extent of the potential impact of MI on the psychosocial measures in the group data from the current study ranged from medium to large (i.e., effect sizes were mostly in the range of 0.5 and 0.8). Data on the degree of impact of a standalone MI intervention for youth with type 1 diabetes have not been previously reported; however, meta-analyses of diabetes interventions have reported small to medium effect on diabetes outcomes, such as HbA1c and psychosocial outcomes

(Hampson et al., 2000; Winkley et al., 2006). This suggests that MI may be effective and potentially more beneficial than other interventions for youth, given the moderate to large effects obtained in the current study. Future research is recommended to further investigate the effect of MI on psychosocial functioning.

The overall findings of this MI study are consistent with previous research (Channon et al., 2003; Huws-Thomas, 2007), and the current thesis contributes to knowledge in this area by addressing gaps in previous research, such as the lack of fidelity measures, clinical significance analysis, and evaluation of MI as a stand-alone intervention. Further research, however, is required to generalise the findings for the youth population. At present, there are only three studies (including the current research) that have investigated the efficacy of MI for youth with type 1 diabetes. Thus, MI research in the context of diabetes interventions for youth is still at infancy. The current evidence, nonetheless, shows that MI maybe a promising intervention for youth with type 1 diabetes. As well as benefiting individual youth and their families, MI has the potential to be of benefit more broadly because many of the healthcare costs associated with diabetes stem from the complications arising from poorly controlled diabetes.

“Type 1 diabetes (T1D) in children and young people is increasing worldwide ... Effective glycaemic control requires a careful balancing act between insulin, food and physical activity. Intensive regimens offer the best possible control; however, they are oppressive for children, young people and families. Fewer than one in six children and young people achieve glycosylated fraction of haemoglobin (HbA1c) values in the range identified as providing best future outcomes. One-third have a HbA1c value that puts them at significant

risk for development of long-term complications. Moderate evidence supports the effectiveness of psychological interventions...There is an urgent need for clinic-based pragmatic, feasible and effective interventions that improve both glycaemic control and quality of life (QoL).” (Christie et al., 2014, p. xxvii)



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## APPENDICES

### Appendix 1.1: Invitation Letters, Information Sheets, and Consent Forms

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#### Invitation letter for Participation in a Research Study

##### *"Youth with Type 1 diabetes"*

Dear .....

We are writing to invite you to take part in a study of youth with Type 1 diabetes. This study is voluntary and obligation free. It is your choice to take part or not.

The title of the study is *Youth with Type 1 diabetes*. Enclosed with this invitation letter is an information sheet, which tells you more about the study and has contact details if you wish to ask any questions in relation to the study. Also enclosed with this letter are: a prepaid envelope, a consent form and the research study questionnaires.

If you decide to participate, please sign the attached consent form. Following this, please return the completed questionnaires as well as the consent form in the enclosed prepaid and addressed envelope. There are three short questionnaires. It is estimated that it may take you around 15 minutes to complete all the questionnaires.

This research is supervised by two academic staff at the University of Canterbury in the Health Sciences Centre – Dr Eileen Britt and Dr Mark Wallace-Bell. The study procedures will be carried out by a postgraduate student, Balsam Obaid.

Participation is confidential. Study information will be kept in a secure location at the University of Canterbury. The results of the study may be published or presented at professional meetings, but your identity will not be revealed.

Participants will receive a \$10 supermarket voucher as a reimbursement. Taking part in the study is your decision. You do not have to be in this study if you do not want to. You may also decide to stop participating at any time. However, this study has potential benefits, which can be found in the enclosed information sheet.

With kind regards,

Balsam Obaid

This study has been reviewed and approved by: the Upper South B Regional Ethics Committee, ethics reference number (URB/10/EXP/048) and the University of Canterbury Human ethics Committee, HEC APPLICATION 2010/183.

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## Information Sheet for Participation in a Research Study

### ***"Youth with Type 1 diabetes"***

*Researcher: Balsam Obaid, Postgraduate Student, Health Sciences Centre, University of Canterbury [bho23@uclive.ac.nz].*

*Supervisors: Dr Eileen Britt, Dr Mark Wallace-Bell, Health Sciences Centre, University of Canterbury [03 3667001 extn: 3687].*

You are invited to take part in a research study to learn more about specific characteristics related to youth with Type 1 diabetes (psychosocial characteristics). Your participation in this study is completely voluntary (your choice). If you agree to take part you may withdraw at any time, for any reason and this will in no way affect your future health care. If you decide to participate, please sign the enclosed consent form within two weeks from the date of the invitation letter.

Here's some more information about the study...

**What is the study about? What are the aims of this study?** Having diabetes at a young age can be tough; learning more about young people who have Type 1 diabetes can help researchers and clinicians to understand youth's needs in a better way.

Our focus in this part of the study is to investigate some of the characteristics of adolescents and young adults with Type 1 diabetes. Additionally, we would like to find out how these characteristics relate to diabetes self-control.

**What are the study procedures? What will I be asked to do?** To able to learn more about some of the characteristics of youth with Type 1 diabetes, participating youth will be invited to complete four brief questionnaires\*; the estimated time to complete these questionnaires is around 15 minutes. For example, the questionnaires have a scale that corresponds to different levels, for instance a scale from 0 (weak) to 5 (strong). You can circle an answer that you think is the most appropriate. These questionnaires will be used to assess topics related to young people's diabetes. These topics are: self-confidence in diabetes management, how being diabetic affects your life (quality of life), and how you perceive diabetes.

\*The questionnaires have been developed for use with people with diabetes - most of the questionnaires were designed in the USA, and hence may contain different wording to what you are familiar with.

**Who can participate in this study?** Youth aged between 15 and 24, who are diagnosed with Type 1 diabetes.

**Who cannot participate in this study?** Pregnant females and youth who cannot read, speak or understand English to a level required in the questionnaires and participant information sheet/ participant consent form

**How participants were selected for this study, and who selected them?** Participants will be randomly selected from a list. The random selection will be aided by a computer random generation of a list, which means that names will be selected by chance.

**What to do if you would like to participate?** We have included the questionnaires with the invitation letter and information sheet. If you would like to participate, you can simply complete the questionnaires and sign the enclosed consent form and then send them back to us using the prepaid and addressed envelope.

**How many participants will be involved?** We hope at least 85 people will complete the questionnaires.

**Where will the study be held?** This study will be held at the Canterbury University.

**Will I receive compensation for my time in participating?**

Participants who complete the questionnaires will receive a \$10 supermarket voucher. The voucher will be sent to your address within eight working days of the receipt of your completed questionnaires.

**Will my GP know I am in the study?** We prefer to advise your GP that you are involved with this study; however, this is your decision.

### **Risks and Benefits**

**What are the risks of participation?** There are no known risks associated with this part of the study. All data collected will be marked with numbers. No names will be used when the results of this study are published (identities will be kept anonymous). However, in the unlikely event of medical or psychological issues arising as a result of this part of the study, please contact a health care provider that you trust.

**What are the benefits of participation?** Although there are no direct benefits to you by taking part in this study, it is expected that results from this study will lead to more in-depth understanding of the needs of young people with diabetes.

### **Participation**

- Your participation in this study is entirely voluntary (your choice).



### **Compensation**

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

**Where can I get more information about the study?** Please feel free to contact one of the following if you have any questions about this study.

- Balsam Obaid, Health Sciences Centre, College of Education, University of Canterbury, Private Bag 4800, Christchurch 8020. . Email: [bho23@uclive.ac.nz](mailto:bho23@uclive.ac.nz)
- Dr Eileen Britt, Health Sciences Centre, College of Education, University of Canterbury, Private Bag 4800, Christchurch 8020. [03 3667001 extn: 3687]. Email: [eileen.britt@canterbury.ac.nz](mailto:eileen.britt@canterbury.ac.nz)
- Dr Mark Wallace-Bell, Health Sciences Centre, College of Education, University of Canterbury, Private Bag 4800, Christchurch 8020. [03 3667001 extn: 3687]. Email: [mark.wallace-bell@canterbury.ac.nz](mailto:mark.wallace-bell@canterbury.ac.nz)

This study has received ethical approval from **the Upper South B Regional Ethics Committee**, ethics reference number: [URB/10/EXP/048](#).

This study has been also reviewed and approved by **the University of Canterbury Human ethics Committee**, [HEC APPLICATION 2010/183](#).

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## CONSENT FORM

(for clients younger than 16 years and their parents or guardians)

### ***“Youth with Type 1 diabetes”***

You are invited to take part in a research study, which will find out more about specific characteristics of youth with Type 1 diabetes, being conducted by Balsam Obaid, Dr Eileen Britt, and Dr Mark Wallace-Bell.

- I understand that taking part in this study is voluntary and that my child may withdraw from this study at any time and this will in no way affect his/her future health care.
- I have read and I understand the information sheet dated July 2011 for participants taking part in this study.
- I have been given the opportunity to discuss this study. I am satisfied with the answers I have been given.
- I understand that my participation in this study is confidential and that no material which could identify me or my child will be used in any report on this study.
- I have had time to consider whether to take part.
- I know whom to contact if I have any questions about this study.

I agree to my child's GP being informed of my participation in this study.....YES / NO

I wish to receive a copy of the results of this study. ....YES / NO

I understand there will be a significant delay between the information I provide and receiving the results.

I \_\_\_\_\_ (name) assent to my child \_\_\_\_\_ (name)  
taking part in this study.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

This study has been reviewed and approved by: the Upper South B Regional Ethics Committee, ethics reference number (URB/10/EXP/048) and the University of Canterbury Human ethics Committee, HEC APPLICATION 2010/183.

*Youth with Type 1 diabetes*  
*Participant Consent Form: Version 3: 12/07/2011*  
Page 1 of 1

## Health Sciences Centre

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## CONSENT FORM

### *"Youth with Type 1 diabetes"*

You are invited to take part in a research study, which will enable us to learn more about specific characteristics of youth with Type 1 diabetes, being conducted by Balsam Obaid, Dr Eileen Britt, and Dr Mark Wallace-Bell.

- I understand that taking part in this study is voluntary (my choice) and that I may withdraw (pull out of) from this study at any time and this will in no way affect my future health care.
- I have read and I understand the information sheet dated July 2011 for participants taking part in this study.
- I have been given the opportunity to discuss this study. I am satisfied with the answers I have been given.
- I understand that my participation in this study is confidential (secret) and that no material which could identify me will be used in any report on this study.
- I have had time to consider whether to take part.
- I know whom to contact if I have any questions about this study.

I agree to my GP being informed of my participation in this study..... YES / NO

I wish to receive a copy of the results of this study. .... YES / NO

I understand there will be a significant delay between the information I provide and receiving the results.

I \_\_\_\_\_ (print full name) hereby consent to take part in this study.

Date: \_\_\_\_\_ Signature: \_\_\_\_\_

This study has been reviewed and approved by: the Upper South B Regional Ethics Committee, ethics reference number (URB/10/EXP/048) and the University of Canterbury Human ethics Committee, HEC APPLICATION 2010/183.

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### Invitation letter for Participation in a Research Study

#### *"Diabetes self-management for Youth with Type 1 diabetes"*

Dear .....,

We are writing to invite you to take part in a study of youth with Type 1 diabetes. This study is voluntary and obligation free. It is your choice to take part or not.

The title of the study is *Diabetes self-management for youth with Type 1 diabetes*. Enclosed with this invitation letter is an information sheet about this part of the study. The information sheet also has contact details, if you would like to ask us questions with regards to the study.

If you decide to participate, please sign the enclosed consent form and return it in the prepaid and addressed envelope. Participation is confidential. Study information will be kept in a secure location at the University of Canterbury. The results of the study may be published or presented at professional meetings, but your identity will not be revealed.

You will receive a \$170 supermarket voucher to thank you and reimburse you for your time. We will pay this in four lots; the last voucher would be paid upon the completion of the final follow-up. Taking part in the study is your decision. You do not have to be in this study if you do not want to. You may also decide to stop participating at any time. However, this study has potential benefits, which can be found in the enclosed information sheet.

With kind regards,

Balsam Obaid

This study has been reviewed and approved by: the Upper South B Regional Ethics Committee, ethics reference number: URB/10/EXP/048 and the University of Canterbury Human ethics Committee, HEC APPLICATION 2010/183.

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## Information Sheet for Participation in a Research Study

### ***"Diabetes self-management for youth with Type 1 diabetes"***

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*Researcher: Balsam Obaid, Postgraduate Student, Health Sciences Centre, University of Canterbury [balsam.obaid@pg.canterbury.ac.nz].*

*Supervisors: Dr Eileen Britt, Dr Mark Wallace-Bell, Health Sciences Centre, University of Canterbury [eileen.britt@canterbury.ac.nz; 03 3667001 extn: 3687].*

---

You are invited to take part in a research study to investigate the effectiveness of using an interviewing style known to help in promoting positive diabetes self-management. This interviewing style is called Motivational Interviewing (MI). Your participation in this study is completely voluntary (your choice). If you agree to take part you may withdraw at any time, for any reason and this will in no way affect your future health care. If you decide to participate, please sign the enclosed form within three weeks from the date of this letter.

Here's some more information about the study...

**What is the study about? What are the aims of this study?** Having diabetes at a young age can be tough; learning more about young people who have Type 1 diabetes can help researchers and clinicians to understand youth's needs in a better way.

Our focus in this part of the research is to study the effectiveness of Motivational Interviewing in facilitating healthier diabetes self-management.

**How participants were selected for this study, and who selected them?** Participants will be selected from a list of youth who have an HbA1c value above certain levels. For those who choose to take part in the study, they will consent for their participation.

**How many participants will be involved?** We hope that at least 9 people will take part in this study.

**Who can participate in this study?** Youth aged between 15 and 24 (inclusive), who are diagnosed with Type 1 diabetes for a year or more.

**Who cannot participate in this study?** Pregnant females, youth who suffer from severe depression, and youth who cannot read, speak or understand English to a level required in the questionnaires and participant information sheet/participant consent form.

**Where will the study be held?** This study will be held at the Canterbury University. The interviewing sessions will be arranged in the Health Sciences Centre at the University of Canterbury.

**Will I receive compensation for my time in participating?**  
Participants will receive a \$170 supermarket voucher to reimburse them for their time and travel expenses. This will be paid in four lots: \$30, \$50, \$40, and the final \$50 will be paid upon the completion of the final follow-up.

**What are the study procedures? What will I be asked to do?**  
Over 13 months we will take only about 12 contact hours of your time! The following list explains what will be required of you as well as the estimated time span:

***Starting weeks (weeks 1, week 2, and week 3):***

1. We would like to you to fill out a set of questionnaires\*. These may take around 15 minutes to fill out. We can mail these to you or organise an option that is more convenient for you.
2. Once a week for three weeks we would like to arrange a time to give you a phone call to ask a few questions in relation to your diabetes self-control during the past day (the day prior to the phone call). The phone call might take around 15 to 20 minutes.
3. Additionally, we would like to collect data from your blood glucose meter (past 7 days).
4. We would also require a blood test sample to measure the current level of HbA1c (we will arrange for this test\*\*), unless you had a blood test very recently.

\* The questionnaires have been developed for use with people with diabetes - most of the questionnaires were designed in the USA, and hence may contain different wording to what you are familiar with.

\*\*All blood tests will be taken by a qualified technical staff member at Canterbury Health Laboratories (CHL) in one of the CHL service rooms. This will be free for you; costs are covered. The taken samples will be held for approximately 7 days, and then they will be sent in biohazard bins to be commercially incinerated (standard method). Upon request, blood samples can be disposed of according to appropriate karakia. The blood samples will be requested from the laboratory and then disposed of in a culturally appropriate manner.

***After the starting weeks, four interviewing sessions will be arranged over two months:***

1. We will arrange with you a time for you to come and see us in the Health Science Centre at the College of Education Campus (we will send you a map that is easy to follow). We will arrange a meeting with you once in each of weeks 1, 2, 4 and 8 over the 2 month period. Each interview might take around 30 to 40 minutes. The interviews will be conducted by professional people (the research study supervisors). We will audio-record the sessions and then transcribe them. We will keep the files in safe and password-protected computers. No identifiable information will be revealed.
2. During this period, we would also like to collect data from your blood glucose meter and to know more in relation to your diabetes self-management. In order to do this, we will undertake

*Diabetes self-management for youth with Type 1 diabetes  
Participant Information Sheet: Version 5: 14/03/2012  
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similar interviews as those in the starting weeks; we would like to conduct an interview in each week of the 8 week period.

***After the interviewing sessions:***

We would then like to collect follow-up information 5 times spread over the following 12 months. The follow-ups are at 2 weeks, then 3, 6, 9, and 12 months. During each follow-up **we would:**

1. Require a further blood test sample to determine a recent HbA1c level (we will arrange for this test, as we did in the starting weeks).
2. Like you to fill out a further set of questionnaires (the same set that you filled out earlier).
3. Know more about your diabetes self-management through an interview and we would like to gather data from your blood glucose meter (past 7 days).

Finally, at six months past the end of MI sessions weeks, we would like to arrange a time with you to attend a one-off session, which lasts for about 30-40 minutes.

**What do I do if I would like to participate?** If you would like to participate, simply sign the enclosed consent form within three weeks from the date of receiving this letter. You can send the signed consent form back to us using the enclosed prepaid and addressed envelope.

**Will my GP and/or the Christchurch Diabetes Centre know I am in the study?** We prefer to advise your GP/the Christchurch Diabetes Centre that you are involved with this study; however, this is your decision.

**Risks and Benefits**

**What are the risks of participation?** There are no known risks associated with this part of the study; however, there can be a very small possibility of complications arising from blood tests, such as dizziness, fainting, bruising, bleeding and, very rarely, an infection or blood accumulating under the skin. The Canterbury Health Laboratories staff are highly trained and experienced, and offer expert assistance and advice. The required blood test is the usual blood test that you have to measure your HbA1c levels.

All data collected will be confidential. No names will be used when the results of this study are published (identities will be anonymous).

In the unlikely event of medical or psychological issues arising as a result of your participation in the study, please contact a health care provider that you trust.

**What are the benefits of participation?** As well as being of potential benefit to the individual patients and their families, the proposed project has the potential to advance knowledge in relevant research areas. The potential benefits of assisting youth with Type 1 diabetes are significant given that it is likely that unhealthy diabetes control during adolescence will impact on the timing and development of the longer term complications of diabetes.



## Participation

- Your participation in this study is entirely voluntary (your choice).
- If you agree to take part, you are free to withdraw from this study at any time, for any reason.
- If you choose not to take part or to withdraw, this will not affect any of your future care or treatment. We will refer you back to your general practitioner or other health professionals as appropriate.
- You may have a friend, family or whanau support to help you understand the risk and/or benefits of this study and any other explanations you require.

If you have any queries or concerns about your rights as a participant in this study you are free to contact the Health and Disability Advocate Service,  
Free phone: 0800 555 050,  
Free fax: 0800 2 SUPPORT (0800 2787 7678)  
Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

## Confidentiality

No material which could personally identify you will be used in any reports based on this study. The data from this study will be available only to the study investigators. All data will be stored in secure areas for at least ten years as required by law.

## Results

**How can I get results of this research?** When this study is over you may have a summary of the key results. Detailed results will be published in international scientific journals. Additionally, a PhD is a public document, which can be accessed via the UC Library database

## Compensation

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

**Where can I get more information about the study?** Please feel free to contact one of the following if you have any questions about this study.



- Balsam Obaid, Health Sciences Centre, College of Education University of Canterbury, Private Bag 4800, Christchurch 8020. [balsam.obaid@pg.canterbury.ac.nz]. OR
- Dr Eileen Britt, Health Sciences Centre, College of Education University of Canterbury, Private Bag 4800, Christchurch 8020. [eileen.britt@canterbury.ac.nz; 03 3667001 extn: 3687]. OR
- Dr Mark Wallace-Bell, Health Sciences Centre, College of Education University of Canterbury, Private Bag 4800, Christchurch 8020. [mark.wallace-bell@canterbury.ac.nz; 03 3667001 extn: 3687].

Address for Canterbury Health Laboratories: Corner Hagley Ave and Tuam Street, **Phone:** (03) 364 0300; 0800 843 522. *Other Locations:* Cashmere (Princesses Margret Hospital); Burwood (Burwood Hospital); Ashburton (Ashburton Hospital).

This study has received ethical approval from the **Upper South B Ethics Regional Committee**, ethics reference number: URB/10/EXP/048.

This study has been also reviewed and approved by the **University of Canterbury Human ethics Committee**, HEC APPLICATION 2010/183.

## CONSENT FORM

### *"Diabetes self-management for Youth with Type 1 diabetes"*

You are invited to take part in a research study, which will enable us to learn more the effectiveness of using Motivational Interviewing (MI) in promoting positive diabetes self-management. This research is conducted by Balsam Obaid, Dr Eileen Britt, and Dr Mark Wallace-Bell.

- I have read and I understand the information sheet dated March 2012 for participants taking part in this study.
- I have been given the opportunity to discuss this study. I am satisfied with the answers I have been given.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my future health care.
- I understand that my participation in this study is confidential and that no material which could identify me will be used in any report on this study.
- I have had time to consider whether to take part.
- I know whom to contact if I have any questions about this study.

I consent to my interviews being audio-recorded and transcribed. ....YES / NO

I give permission for the research investigators to have access to my blood test results and/or questionnaire notes where it is relevant to my taking part in the research..... YES / NO

I agree to my GP/the Christchurch Diabetes Centre being informed of my participation in this study .....YES / NO

If applicable, please circle one of the following options: I would like my blood samples to be disposed of

- Using standard disposal methods (this is the default method if an option is not circled – please refer to the information sheet)
- Disposed with appropriate karakia; I consent for my blood samples to be requested from the Canterbury Health Laboratory and then disposed of in a culturally appropriate manner.

I wish to receive a copy of the results of this study. ....YES / NO

*I understand there will be a significant delay between the information I provide and receiving the results.*

.....(print full name) hereby consent to take part in this study.

Date: \_\_\_\_\_ Phone number: \_\_\_\_\_ Email address: \_\_\_\_\_

Signature: \_\_\_\_\_ Signature of witness: \_\_\_\_\_

This study has been reviewed and approved by: the Upper South B Regional Ethics Committee, ethics reference number (URB/10/EXP/048) and the University of Canterbury Human ethics Committee, HEC APPLICATION 2010/183.

## Appendix 2.1: Prevalence (Crude, Age-Specific, and Age-Standardised) and Age-Standardised Prevalence Ratio (Boniol & Heanue, 2007; Boyle & Parkin, 1991)

Crude prevalence =  $d / y$

Where

$d$  = number of cases observed in a certain year

$y$  = total population in the same year

Age-specific prevalence =  $d_i / y_i$

Where

$d_i$  = number of cases observed in a certain year for the  $i^{\text{th}}$  specific age range

$y_i$  = total population in the same year for the  $i^{\text{th}}$  specific age range

Age-standardised prevalence (ASP) =  $\frac{\sum_i w_i d_i / y_i}{\sum_i w_i}$

Where

$d_i$  = number of cases observed in a certain year for the  $i^{\text{th}}$  specific age range

$y_i$  = total population in the same year for the  $i^{\text{th}}$  specific age range

$w_i$  = the weight applied to the  $i^{\text{th}}$  age group and is the size of the reference population in the  $i^{\text{th}}$  age group. It is the total reference population in the  $i^{\text{th}}$  age range

The age-standardised prevalence ratio (ASPR) is a ratio of two age-standardised prevalences ( $ASP_1$  and  $ASP_2$ ) estimated at, for example, two time points (e.g., 2003 and 2010). A confidence interval (CI) is established for the ASPR (for example, 95% CI) using

$$(ASP_1/ASP_2)^{1 \pm (Z_{\alpha/2}/X)}$$

Where

$$X = \frac{(ASP_1 - ASP_2)}{\sqrt{VAR(ASP_1) + VAR(ASP_2)}}$$

$Z_{\alpha/2} = 1.96$  (at the 95% level)

$VAR(ASP_i)$  = variance which is the standard error squared and is given by

$$Var(ASP) = \frac{\sum_{i=1} \left( \frac{d_i * (y_i - d_i) * w_i^2}{y_i^3} \right)}{\left( \sum_{i=1} w_i \right)^2}$$

If the 95% CI includes one, then the  $ASP_1$  and  $ASP_2$  are not significantly different at the 5% level. That is, the observed ratio is not significantly different from unity.

## Appendix 3.1: Questionnaires

### The B-IP Questionnaire

For the following questions, please circle the number that best corresponds to your views:

<b>How much does your diabetes affect your life?</b>										
0	1	2	3	4	5	6	7	8	9	10
no affect at all								severely affects my life		
<b>How long do you think your diabetes will continue?</b>										
0	1	2	3	4	5	6	7	8	9	10
a very short time								forever		
<b>How much control do you feel you have over your diabetes?</b>										
0	1	2	3	4	5	6	7	8	9	10
Absolutely no control								extreme amount of control		
<b>How much do you think your treatment can help your diabetes?</b>										
0	1	2	3	4	5	6	7	8	9	10
not at all								extremely helpful		
<b>How much do you experience symptoms from your diabetes?</b>										
0	1	2	3	4	5	6	7	8	9	10
no symptoms at all								many severe symptoms		
<b>How concerned are you about your diabetes?</b>										
0	1	2	3	4	5	6	7	8	9	10
not at all concerned								extremely concerned		
<b>How well do you feel you understand your diabetes?</b>										
0	1	2	3	4	5	6	7	8	9	10
don't understand at all								Understand very clearly		
<b>How much does your diabetes affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)</b>										
0	1	2	3	4	5	6	7	8	9	10
not at all affected emotionally								extremely affected emotionally		

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ID \_\_\_\_\_ Form \_\_\_\_\_

Date \_\_\_\_\_

**CONFIDENCE IN DIABETES SELF-CARE****TYPE 1****Instructions:**

After each of the following statements, circle the number that best indicates how much YOU BELIEVE you can or cannot do what is asked. Please note that the questions ask not what you should do but what you BELIEVE you can do.

**I believe I can:**

	No, I am sure I cannot	No, I don't think I can	I am not sure	Yes, I think I can	Yes, I am sure I can
1. ...plan my meals and snacks according to dietary guidelines.	1	2	3	4	5
2. ...check my blood glucose at least 2 times a day.	1	2	3	4	5
3. ...perform the prescribed number of daily insulin injections.	1	2	3	4	5
4. ...adjust my insulin for exercise, traveling, or celebrations.	1	2	3	4	5
5. ...adjust my insulin when I am sick.	1	2	3	4	5
6. ...detect <i>high</i> levels of blood sugar in time to correct.	1	2	3	4	5
7. ...detect <i>low</i> levels of blood sugar in time to correct.	1	2	3	4	5
8. ...treat a <i>high</i> blood sugar correctly.	1	2	3	4	5
9. ...treat a <i>low</i> blood sugar correctly.	1	2	3	4	5
10. ...keep daily records of my blood sugars.	1	2	3	4	5
11. ...decide when it's necessary to contact my doctor or diabetes educator.	1	2	3	4	5
12. ...ask my doctor questions about my treatment plan.	1	2	3	4	5
13. ...keep my blood glucose in the normal range when under stress.	1	2	3	4	5
14. ...check my feet for sores or blisters every day.	1	2	3	4	5
15. ...ask my friends or relatives for help with my diabetes.	1	2	3	4	5
16. ...inform colleagues/others of my diabetes, if needed.	1	2	3	4	5
17. ...keep my medical appointments.	1	2	3	4	5
18. ...exercise 2 to 3 times weekly.	1	2	3	4	5
19. ...figure out what foods to eat when I am dining out.	1	2	3	4	5
20. ...read and hear about diabetes complications without getting discouraged.	1	2	3	4	5
21. ...manage my diabetes well overall.	1	2	3	4	5

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ID# \_\_\_\_\_

Date: \_\_\_\_\_

# PedsQL™

## Diabetes Module

Version 3.2

### TEEN REPORT (ages 13-18)

#### DIRECTIONS

Teens with diabetes sometimes have special problems. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

- 0** if it is **never** a problem
- 1** if it is **almost never** a problem
- 2** if it is **sometimes** a problem
- 3** if it is **often** a problem
- 4** if it is **almost always** a problem

There are no right or wrong answers.  
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has this been for you ...

<b>ABOUT MY DIABETES (problems with...)</b>	<b>Never</b>	<b>Almost Never</b>	<b>Some times</b>	<b>Often</b>	<b>Almost Always</b>
1. I feel hungry	0	1	2	3	4
2. I feel thirsty	0	1	2	3	4
3. I have to go to the bathroom too often	0	1	2	3	4
4. I have stomachaches	0	1	2	3	4
5. I have headaches	0	1	2	3	4
6. I feel like I need to throw up	0	1	2	3	4
7. I go "low"	0	1	2	3	4
8. I go "high"	0	1	2	3	4
9. I feel tired	0	1	2	3	4
10. I get shaky	0	1	2	3	4
11. I get sweaty	0	1	2	3	4
12. I feel dizzy	0	1	2	3	4
13. I feel weak	0	1	2	3	4
14. I have trouble sleeping	0	1	2	3	4
15. I get cranky or grumpy	0	1	2	3	4

In the past **ONE month**, how much of a **problem** has this been for you ...

<b>TREATMENT - I (problems with...)</b>	<b>Never</b>	<b>Almost Never</b>	<b>Some times</b>	<b>Often</b>	<b>Almost Always</b>
1. It hurts to get my finger pricked	0	1	2	3	4
2. It hurts to get insulin shots	0	1	2	3	4
3. I am embarrassed by my diabetes treatment	0	1	2	3	4
4. My parents and I argue about my diabetes care	0	1	2	3	4
5. It is hard for me to do everything I need to do to care for my diabetes	0	1	2	3	4

Whether you do these things **on your own or with the help of your parents**, please answer how hard these things were to do in the past **ONE month**.

<b>TREATMENT II - (problems with...)</b>	<b>Never</b>	<b>Almost Never</b>	<b>Some times</b>	<b>Often</b>	<b>Almost Always</b>
1. It is hard for me to take blood glucose tests	0	1	2	3	4
2. It is hard for me to take insulin shots	0	1	2	3	4
3. It is hard for me to exercise or do sports	0	1	2	3	4
4. It is hard for me to keep track of carbohydrates	0	1	2	3	4
5. It is hard for me to carry a fast-acting carbohydrate	0	1	2	3	4
6. It is hard for me to snack when I go "low"	0	1	2	3	4



In the past **ONE month**, how much of a **problem** has this been for you ...

<b>WORRY (problems with...)</b>	<b>Never</b>	<b>Almost Never</b>	<b>Some times</b>	<b>Often</b>	<b>Almost Always</b>
1. I worry about going "low"	0	1	2	3	4
2. I worry about going "high"	0	1	2	3	4
3. I worry about long-term complications from diabetes	0	1	2	3	4

In the past **ONE month**, how much of a **problem** has this been for you ...

<b>COMMUNICATION (problems with...)</b>	<b>Never</b>	<b>Almost Never</b>	<b>Some times</b>	<b>Often</b>	<b>Almost Always</b>
1. It is hard for me to tell the doctors and nurses how I feel	0	1	2	3	4
2. It is hard for me to ask the doctors and nurses questions	0	1	2	3	4
3. It is hard for me to explain my illness to other people	0	1	2	3	4
4. I am embarrassed about having diabetes	0	1	2	3	4

ID# \_\_\_\_\_

Date: \_\_\_\_\_

# PedsQL™

## Diabetes Module

Version 3.2

### ADULT REPORT

#### DIRECTIONS

Adults with diabetes sometimes have special problems. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

- 0** if it is **never** a problem
- 1** if it is **almost never** a problem
- 2** if it is **sometimes** a problem
- 3** if it is **often** a problem
- 4** if it is **almost always** a problem

There are no right or wrong answers.  
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has this been for you ...

ABOUT MY DIABETES (problems with...)	Never	Almost Never	Some times	Often	Almost Always
1. I feel hungry	0	1	2	3	4
2. I feel thirsty	0	1	2	3	4
3. I have to go to the bathroom too often	0	1	2	3	4
4. I have stomachaches	0	1	2	3	4
5. I have headaches	0	1	2	3	4
6. I feel like I need to throw up	0	1	2	3	4
7. I go "low"	0	1	2	3	4
8. I go "high"	0	1	2	3	4
9. I feel tired	0	1	2	3	4
10. I get shaky	0	1	2	3	4
11. I get sweaty	0	1	2	3	4
12. I feel dizzy	0	1	2	3	4
13. I feel weak	0	1	2	3	4
14. I have trouble sleeping	0	1	2	3	4
15. I get cranky or grumpy	0	1	2	3	4

In the past **ONE month**, how much of a **problem** has this been for you ...

TREATMENT - I (problems with...)	Never	Almost Never	Some times	Often	Almost Always
1. It hurts to get my finger pricked	0	1	2	3	4
2. It hurts to get insulin shots	0	1	2	3	4
3. I am embarrassed by my diabetes treatment	0	1	2	3	4
4. My spouse, significant other, and/or other family members and I argue about my diabetes care	0	1	2	3	4
5. It is hard for me to do everything I need to do to care for my diabetes	0	1	2	3	4

Please answer how hard these things were to do in the past **ONE month**.

TREATMENT II - (problems with...)	Never	Almost Never	Some times	Often	Almost Always
1. It is hard for me to take blood glucose tests	0	1	2	3	4
2. It is hard for me to take insulin shots	0	1	2	3	4
3. It is hard for me to exercise	0	1	2	3	4
4. It is hard for me to keep track of carbohydrates	0	1	2	3	4
5. It is hard for me to carry a fast-acting carbohydrate	0	1	2	3	4
6. It is hard for me to snack when I go "low"	0	1	2	3	4

In the past **ONE month**, how much of a **problem** has this been for you ...

<b>WORRY (problems with...)</b>	<b>Never</b>	<b>Almost Never</b>	<b>Some- times</b>	<b>Often</b>	<b>Almost Always</b>
1. I worry about going "low"	0	1	2	3	4
2. I worry about going "high"	0	1	2	3	4
3. I worry about long-term complications from diabetes	0	1	2	3	4

In the past **ONE month**, how much of a **problem** has this been for you ...

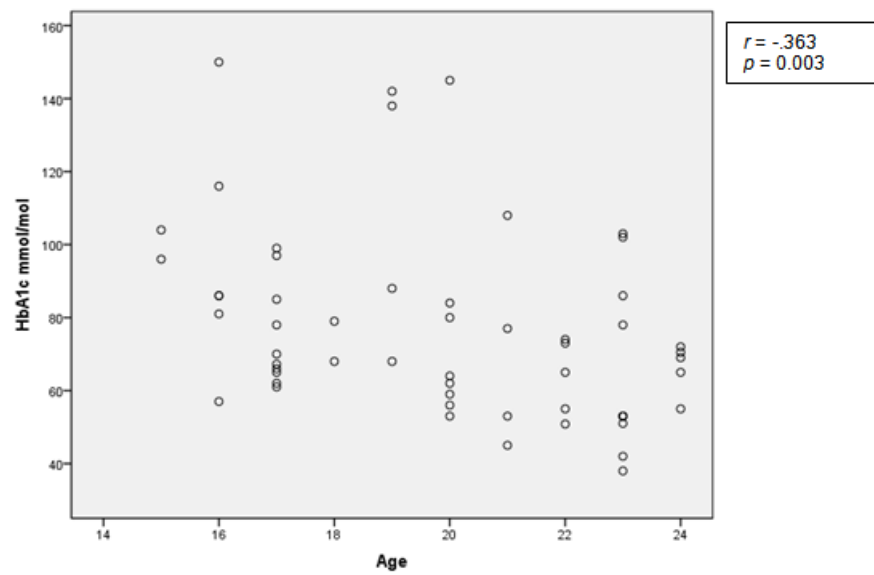
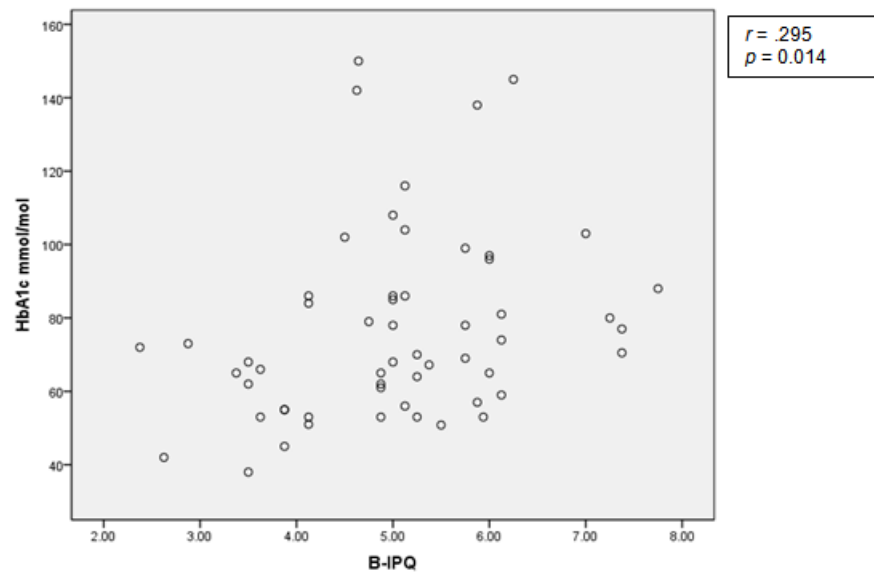
<b>COMMUNICATION (problems with...)</b>	<b>Never</b>	<b>Almost Never</b>	<b>Some- times</b>	<b>Often</b>	<b>Almost Always</b>
1. It is hard for me to tell the doctors and nurses how I feel	0	1	2	3	4
2. It is hard for me to ask the doctors and nurses questions	0	1	2	3	4
3. It is hard for me to explain my illness to other people	0	1	2	3	4
4. I am embarrassed about having diabetes	0	1	2	3	4

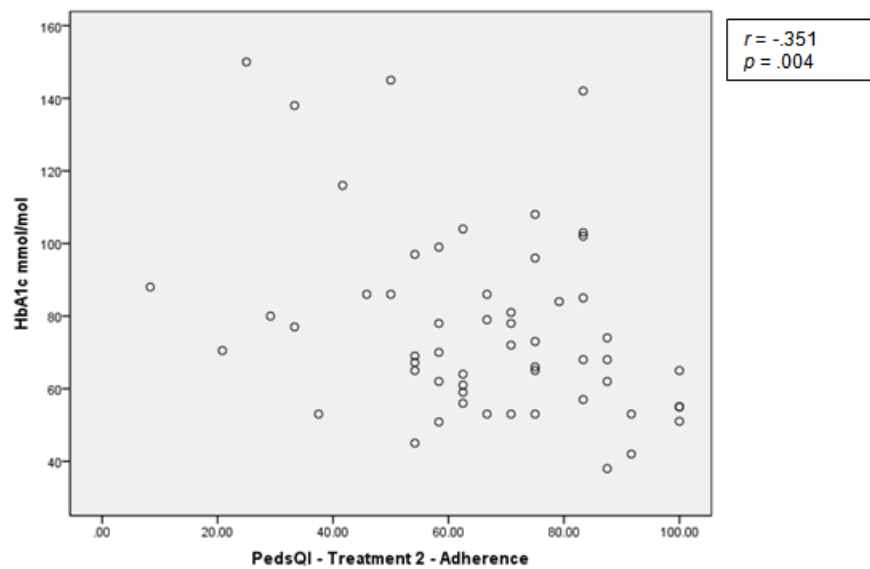
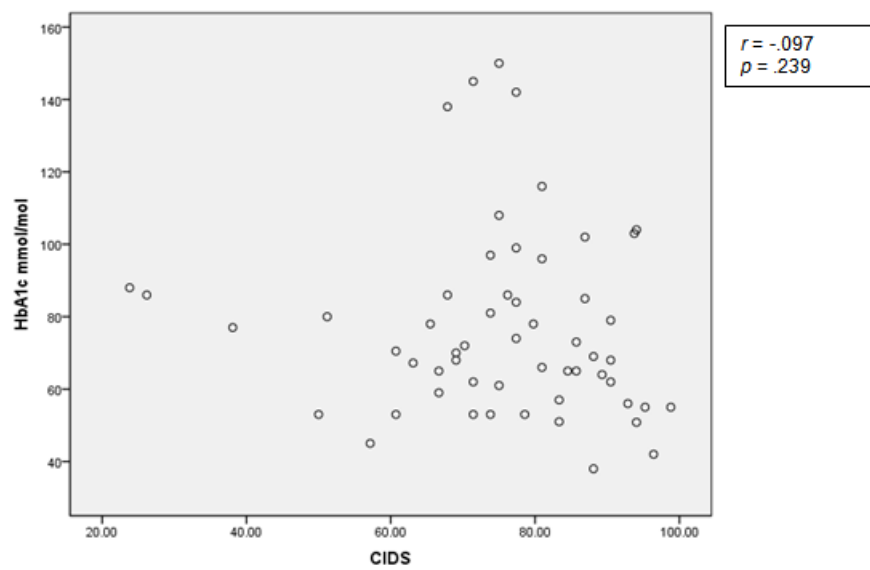
## Appendix 3.2: Bivariate Correlations Among HbA1c, Age, CIDS, BIPQ, and PedsQL

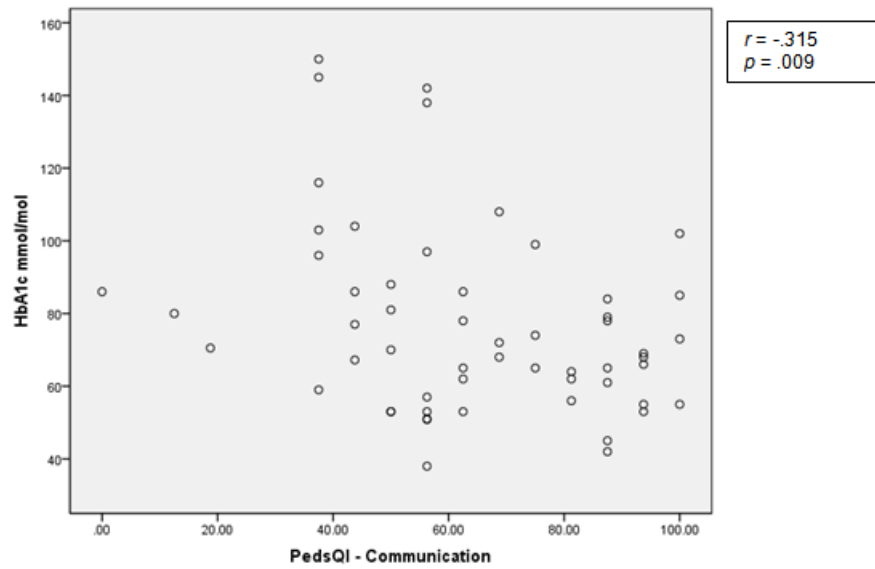
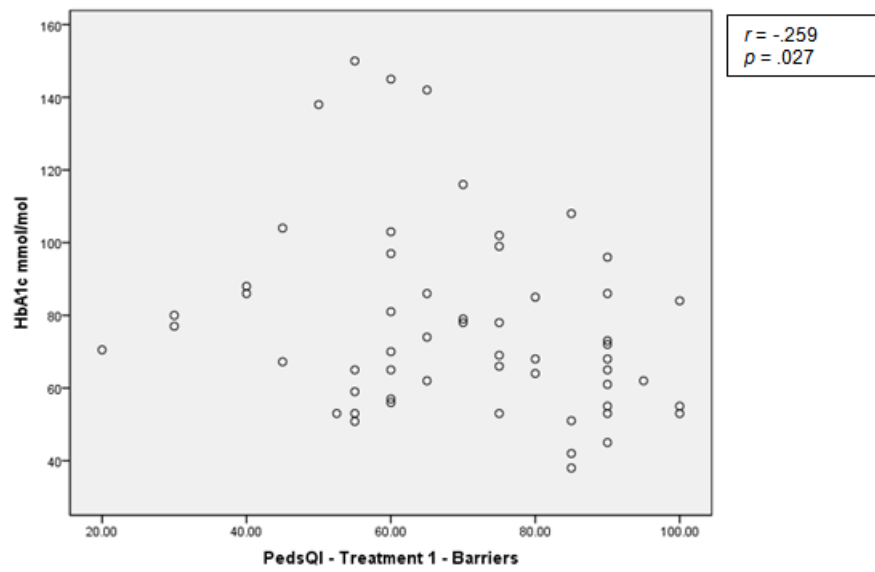
Pearson Correlation		Correlations																
	HbA1c mmol/mol	Age (years)	CIDS	BIPQ - Total score	BIPQ - Consequences	BIPQ - Timeline	BIPQ - Personal control (R)	BIPQ - Treatment control (R)	BIPQ - Identity	BIPQ - Concern	BIPQ - Coherence (R)	BIPQ - Emotions	PedsQL - Diabetes symptoms	PedsQL - Worry	PedsQL - Treatment barriers	PedsQL - Treatment adherence	PedsQL - Communication	PedsQL - Total score
HbA1c mmol/mol	1																	
Age (years)	-.363**	1																
CIDS	-.097	.095	1															
BIPQ - Total score	.295*	-.168	-.428**	1														
BIPQ - Consequences	.116	-.153	-.161	.617**	1													
BIPQ - Timeline	.187	-.231	-.049	.201	.066	1												
BIPQ - Personal control (R)	.363**	-.045	-.528**	.600**	.012	.248	1											
BIPQ - Treatment control (R)	.124	.147	-.268*	.536**	.236	.237	.409**	1										
BIPQ - Identity	.236	-.378**	-.159	.578**	.434**	.029	.270*	.133	1									
BIPQ - Concern	.027	.125	-.145	.556**	.302*	-.180	.108	.148	.198	1								
BIPQ - Coherence (R)	.282*	-.200	-.405**	.578**	.158	.136	.441*	.252	.133	.161	1							
BIPQ - Emotions	.177	-.171	-.197	.729**	.529**	-.101	.225	.127	.377**	.475**	.325*	1						
PedsQL - Diabetes symptoms	-.193	.257	.230	-.589**	-.451**	.059	-.330*	-.252	-.615**	-.195	-.285*	-.485**	1					
PedsQL - Worry	.087	.079	.246	-.460**	-.285*	.216	-.077	-.081	-.236	-.563**	-.325*	-.473**	.400**	1				
PedsQL - Treatment barriers	-.259	.211	.440**	-.690**	-.461**	-.101	-.424**	-.461**	-.422**	-.255	-.468**	-.501**	.488**	.422**	1			
PedsQL - Treatment adherence	-.351**	.193	.634**	-.614**	-.294*	-.052	-.413**	-.405**	-.389**	-.321*	-.426**	-.468**	.454**	.483**	.657**	1		
PedsQL - Communication	-.315*	.217	.562**	-.552**	-.341*	-.089	-.453**	-.255	-.289*	-.202	-.465**	-.392**	.400**	.333*	.623**	.562**	1	
PedsQL - Total score	-.268*	.243	.568**	-.751**	-.466**	.007	-.441**	-.374**	-.484**	-.410**	-.521**	-.598**	.672**	.701**	.830**	.831**	.784**	1

\*\* . Correlation is significant at the 0.01 level (2-tailed).  
 \* . Correlation is significant at the 0.05 level (2-tailed).

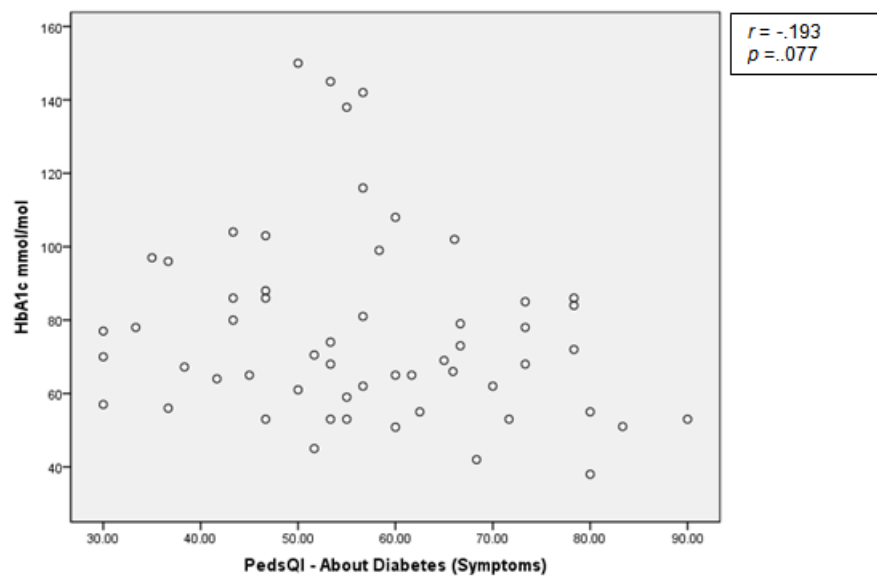
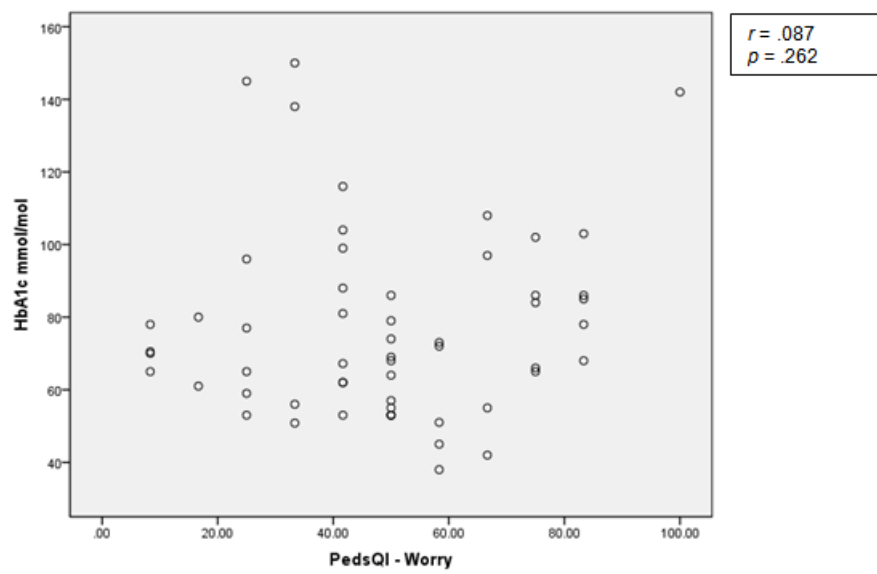
**Appendix 3.3: Scatter Plots and Bivariate Relationships Between HbA1c and  
BIPQ, Age, CIDS, and PedsQL ( $N = 56$ ;  $k = 9$ )**











### Appendix 3.4: Pearson's Correlations Among HbA1c, Age, Gender, BIPQ, CIDS, and PedsQL ( $N = 56$ ; $k = 9$ )

Correlations										
Pearson Correlation										
	HbA1c mmol/mol	Age	Gender	BIPQ-Total	CIDS	PedsQL - Symptoms	PedsQL - Worry	PedsQL - Treatment Barriers	PedsQL - Treatment Adherence	PedsQL - Communication
HbA1c mmol/mol	1	-.363**	-.034	.295*	-.097	-.193	.087	-.259	-.351**	-.315*
Age	-.363**	1	.224	-.168	.095	.257	.079	.211	.193	.217
Gender	-.034	.224	1	-.121	-.203	.331*	.229	.162	.085	-.054
BIPQ-Total	.295*	-.168	-.121	1	-.428**	-.589**	-.460**	-.690**	-.614**	-.552**
CIDS	-.097	.095	-.203	-.428**	1	.230	.246	.440**	.634**	.562**
PedsQL - Symptoms	-.193	.257	.331*	-.589**	.230	1	.400**	.488**	.454**	.400**
PedsQL - Worry	.087	.079	.229	-.460**	.246	.400**	1	.422**	.483**	.333*
PedsQL - Treatment Barriers	-.259	.211	.162	-.690**	.440**	.488**	.422**	1	.657**	.623**
PedsQL - Treatment Adherence	-.351**	.193	.085	-.614**	.634**	.454**	.483**	.657**	1	.562**
PedsQL - Communication	-.315*	.217	-.054	-.552**	.562**	.400**	.333*	.623**	.562**	1

\*\* . Correlation is significant at the 0.01 level (2-tailed).

\* . Correlation is significant at the 0.05 level (2-tailed).

### Appendix 3.5: Pearson's Correlations Among HbA1c, Age, Gender, BIPQ, CIDS, and PedsQL ( $N = 52$ ; $k = 9$ ); Potential Outliers Removed: HbA1c $\geq 138$ mmol/mol

Correlations										
Pearson Correlation										
	HbA1c mmol/mol	Age	Gender	BIPQ-Total	CIDS	PedsQL - Symptoms	PedsQL - Worry	PedsQL - Treatment Barriers	PedsQL - Treatment Adherence	PedsQL - Communication
HbA1c mmol/mol	1	-.389**	-.107	.362**	-.099	-.222	.154	-.194	-.271	-.243
Age	-.389**	1	.217	-.181	.094	.250	.078	.191	.153	.193
Gender	-.107	.217	1	-.138	-.216	.342*	.203	.161	.036	-.046
BIPQ-Total	.362**	-.181	-.138	1	-.424**	-.597**	-.460**	-.697**	-.642**	-.559**
CIDS	-.099	.094	-.216	-.424**	1	.229	.247	.438**	.664**	.571**
PedsQL - Symptoms	-.222	.250	.342*	-.597**	.229	1	.419**	.487**	.465**	.397**
PedsQL - Worry	.154	.078	.203	-.460**	.247	.419**	1	.438**	.452**	.339*
PedsQL - Treatment Barriers	-.194	.191	.161	-.697**	.438**	.487**	.438**	1	.653**	.614**
PedsQL - Treatment Adherence	-.271	.153	.036	-.642**	.664**	.465**	.452**	.653**	1	.552**
PedsQL - Communication	-.243	.193	-.046	-.559**	.571**	.397**	.339*	.614**	.552**	1

\*\* . Correlation is significant at the 0.01 level (2-tailed).

\* . Correlation is significant at the 0.05 level (2-tailed).

## Appendix 4.1: 24hr Recall Interview Assessment Measure

Participant Number:

Interviewer:

Dates/Times of Attempted Interviews:

Date/Time of Interview:

Problems with meter or other self-care equipment:

Describe what you did yesterday from the time you got up until the time you went to bed.

Yesterday morning, did you:

eat a meal?

☐ No

☐ Yes (1)

do a glucose test?

☐ No

☐ Yes (2)

take insulin?

☐ No

☐ Yes (3)      How many minutes before or after eating? ☐ (4)

take the correct amount considering your glucose level and number of carb units?

☐ No

☐ Yes (5)

In the middle of the day yesterday, did you:

eat a meal?

☐ No

☐ Yes (1)

do a glucose test?

☐ No

☐ Yes (2)

take insulin?

☐ No

☐ Yes (3)      How many minutes before or after eating? ☐ (4)

take the correct amount considering your glucose level and number of carb units?

☐ No

☐ Yes (5)

Last night, did you:

eat a meal?

☐ No

☐ Yes (1)

do a glucose test?

☐ No

☐ Yes (2)

take insulin?

☐ No

☐ Yes (3)      How many minutes before or after eating? ☐ (4)

take the correct amount considering your glucose level and number of carb units?

☐ No

☐ Yes (5)

Before bedtime last night, did you:

eat anything containing carbohydrates?

☐ No

☐ Yes (1)

do a glucose test?

☐ No

☐ Yes (2)

take insulin?

☐ No

☐ Yes (3)

## Appendix 4.2: Evaluating Statistical difference and Equivalence Using Inferential Confidence Intervals for Dependent Samples (Tryon, 2001; Tryon & Lewis, 2008, 2009)

### Statistical Difference

The standard formula for the confidence interval (CI) of a mean is

$$\bar{Y} \pm t_v^{\alpha/2} S_{\bar{Y}} = \bar{Y} \pm t_v^{\alpha/2} \frac{S}{\sqrt{n}}.$$

Where

$\bar{Y}$  = mean

$S_{\bar{Y}}$  = standard error of mean

$S$  = standard deviation

$t_v^{\alpha/2}$  = the upper 100(1- $\alpha$ /2) percentile of the  $t$  distribution with  $v$  degrees of freedom and  $\alpha$  significance

$n$  = sample size

Non-overlapping CIs for a pair of means ( $\bar{Y}_1$  and  $\bar{Y}_2$ ) are sufficient but not necessary to determine a significant difference between the means. Tryon (2001) developed the concept of inferential CIs which modify the standard CIs such that a non-overlap of the inferential CIs equates to statistical difference as in a standard  $t$ -test.

A modified inferential CI about each mean,  $\bar{Y}_1$  and  $\bar{Y}_2$  is constructed using a standard  $t$  test and a reduction factor  $E$ . The reduction factor ( $E$ ) is the ratio of the

standard error of the difference between two group means ( $\bar{Y}_1$  and  $\bar{Y}_2$ ) to the sum of the standard errors of both group means:

$$E = \frac{S_{\bar{Y}_2 - \bar{Y}_1}}{S_{\bar{Y}_1} + S_{\bar{Y}_2}}$$

The term  $S_{\bar{Y}_2 - \bar{Y}_1}$  is the estimated standard error for the difference between the group means. For dependent samples this is given by

$$S_{\bar{Y}_2 - \bar{Y}_1} = \sqrt{S_{\bar{Y}_1}^2 + S_{\bar{Y}_2}^2 - 2r_{12}S_{\bar{Y}_1}S_{\bar{Y}_2}},$$

Where  $r_{12}$  is the correlation coefficient between the two samples.

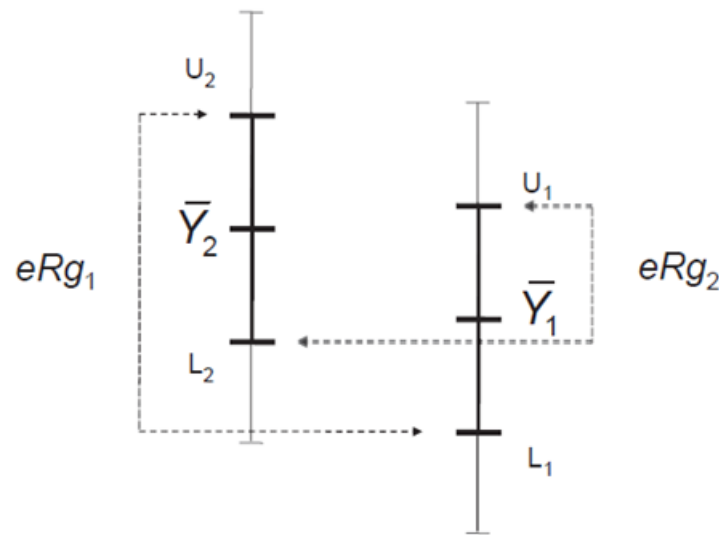
The level of statistical significance can be set, for example, at 5% level of statistical significance for 95% confidence and therefore a critical  $t$  value can be calculated. The inferential CI is then constructed using a proportionately reduced critical  $t$  value. So, the inferential CI for a mean,  $\bar{Y}$ , is calculated from

$$\bar{Y} \pm E t_v^{\alpha/2} \frac{S}{\sqrt{n}}$$

Statistical difference is said to exist between two groups if the two inferential CIs do not overlap; the upper limit of the lesser mean (e.g.,  $\bar{Y}_1$ ) is less than the lower limit of the greater mean (e.g.,  $\bar{Y}_2$ ). The probability value associated with this statistical difference is  $p < .05$  because the critical value for the 5% significance level (95% confidence level) was the initial  $t$  value.

## Statistical Equivalence

Statistical equivalence is when the maximum probable difference estimate (i.e., the upper modified CI limit of the greater mean minus the lower modified CI limit of the lesser mean) or  $eRg$  fits within an inconsequential difference between the two CIs. The inconsequential difference can be based on a delta ( $\Delta$ ) bound of the maximum difference that can be dismissed on substantive ground. Figure A.1 illustrates the statistical equivalence concept.



**Figure A.1** This figure graphically defines the equivalence range ( $eRg$ ) as the larger of two differences between the endpoints of two ICs designated by the heavy lines. Delta is a value that, on substantive grounds, is agreed to be an inconsequential amount. Statistical equivalence occurs when  $eRg \leq \Delta$ . The light lines designate the upper and lower limits of standard 95% confidence intervals. Source of figure and description is Tryon and Lewis (2008, p. 275).

If  $\bar{Y}_2 > \bar{Y}_1$ , then  $eRg_1 > eRg_2$ , so statistical equivalence occurs if and only if:

$$(\bar{Y}_2 - \bar{Y}_1) + E(t_{v_2}^{\alpha/2} S_{Y_2} + t_{v_1}^{\alpha/2} S_{Y_1}) \leq \Delta.$$



#### **Appendix 4.3: Computing the Low Blood Glucose Index (LBGI), High Blood Glucose Index, (HBGI) and, Average Daily Risk Range (ADRR).**

The SMOBG data can be analysed using the risk analysis approach, which include the following steps: symmetrise the blood glucose (BG) measurement scale to correct an inherited asymmetry of the hypoglycaemic versus hyperglycaemic ranges; use a BG risk function to measure the risk associated with a certain BG level; and employ the SMOBG-based risk metrics to interpret the risk analysis results (Cobelli et al., 2009; Kovatchev et al., 1997; Kovatchev et al., 2000; Kovatchev et al., 2006).

##### **Symmetrisation of the BG Measurement Scale**

The BG scale is not symmetric because it has a numerically wider hyperglycaemic range ( $10 < BG < 33.3\text{mmol/L}$ ) compared to the hypoglycaemic range ( $1.1 < BG < 3.9\text{mmol/L}$ ), and the euglycaemic range ( $3.9\text{-}10\text{mmol/L}$ ) is not located at the centre of the data range. The scale asymmetry creates computational issues and analytical challenges; a symmetrisation of the BG scale resolves these issues.

The symmetrisation can be achieved as follows: transform the hyperglycaemic range to have a narrower interval, the hypoglycaemic range to have a wider interval, transfer the target range to a central location around zero, and transform the whole range to have a zero centre. The zero centre is mapped to the BG reading  $6.25\text{mmol/L}$ , which is in the middle of the recommended clinical clustering of the BG values range (i.e.,  $6\text{-}6.5\text{ mmol/L}$ ). These transformations yield a transformed BG scale that has its whole range and target range symmetric around zero. More formally, let  $f(BG)$  be a continuous function defined on the BG range  $[1.1, 33.3]$  such as

$f(BG, \alpha, \beta) = [(\ln(BG))^{\alpha} - \beta]$ ,  $\alpha, \beta > 0$ ; Where  $\alpha = 1.084$ ,  $\beta = 5.381$ , and  $\gamma = 1.509$ .

Briefly, the derivation of this equation was based on an expected logarithmic presentation of the concentration of sugar in the blood (BG levels); solving for the fixed parameters involved selecting convenient values for the minimal and maximal of the transformed range (i.e.,  $-\sqrt{10}$  and  $\sqrt{10}$  respectively). The detailed derivation of this equation is presented in the original articles; it important to note that these parameters are sample independent (Kovatchev et al., 1997; Kovatchev et al., 2000).

### **The BG Risk Function**

The transformed BG values using  $f(BG)$  can be converted into a risk range using a risk function,  $r(BG)$ . This function represents the risk associated with certain BG values. The  $r(BG)$  assigns a numerical weight (0 to 100) and sign (+ or -) depending on the BG value. In other words, the function progressively allocates a numerical weight that depends on the extent of the deviation from the centre zero (i.e., from the optimal target value: 6.25 mmol/L, which has an  $r(BG)$  of 0). This feature accounts for the severity of the deviation from the centre and offers equal emphasis on the ranges of hypoglycaemia and hyperglycaemia. This risk function is used to compute the SMBG risk metrics (presented shortly).

The  $r(BG)$  is computed by superimposing a quadratic function over the transformed BG scale:  $r(BG) = 10 \cdot f(BG)^2$  (Kovatchev et al., 2000). The left branch of the quadratic function parabola identifies the risk of hypoglycaemia, while the right branch identifies the risk of hyperglycaemia. Based on that, we define the low and the high BG Indices as follows:

Let  $x_1, x_2, \dots, x_n$  be a series of  $n$  BG readings, and let

$rl(BG)=r(BG)$  if  $f(BG)<0$  and 0 otherwise;

$rh(BG)=r(BG)$  if  $f(BG)>0$  and 0 otherwise.

### The SMOBG Risk Metrics

The Low Blood Glucose Index (LBGI), and the High BG Index (HBGI) are then defined as:

$$LBGI = \frac{1}{n} \sum_{i=1}^n rl(x_i) \text{ and}$$

$$HBGI = \frac{1}{n} \sum_{i=1}^n rh(x_i) \text{ respectively.}$$

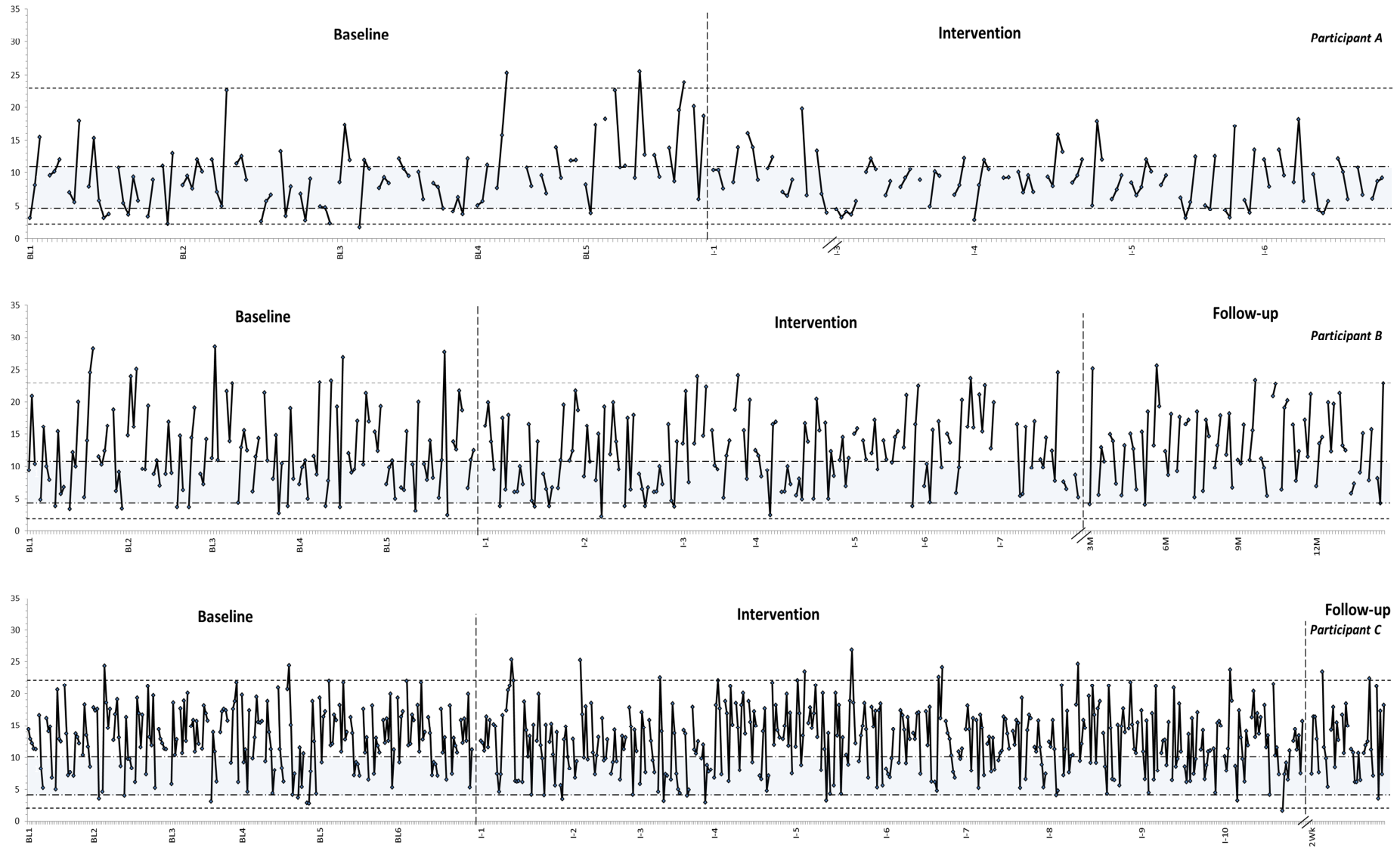
The LBGI and the HBGI measure the risk associated with hypoglycaemia and hyperglycaemia, respectively. An increase in the LBGI score indicates an expected increase in the frequency and/or extent of hypoglycaemic episodes, and increase in HBGI score also indicates an expected increase in the frequency and/or extent of hyperglycaemic episodes (Kovatchev et al., 2002; Kovatchev et al., 2000). These two measures are specifically sensitive to measuring their end of the glycaemia range, and their computations are independent of each other.

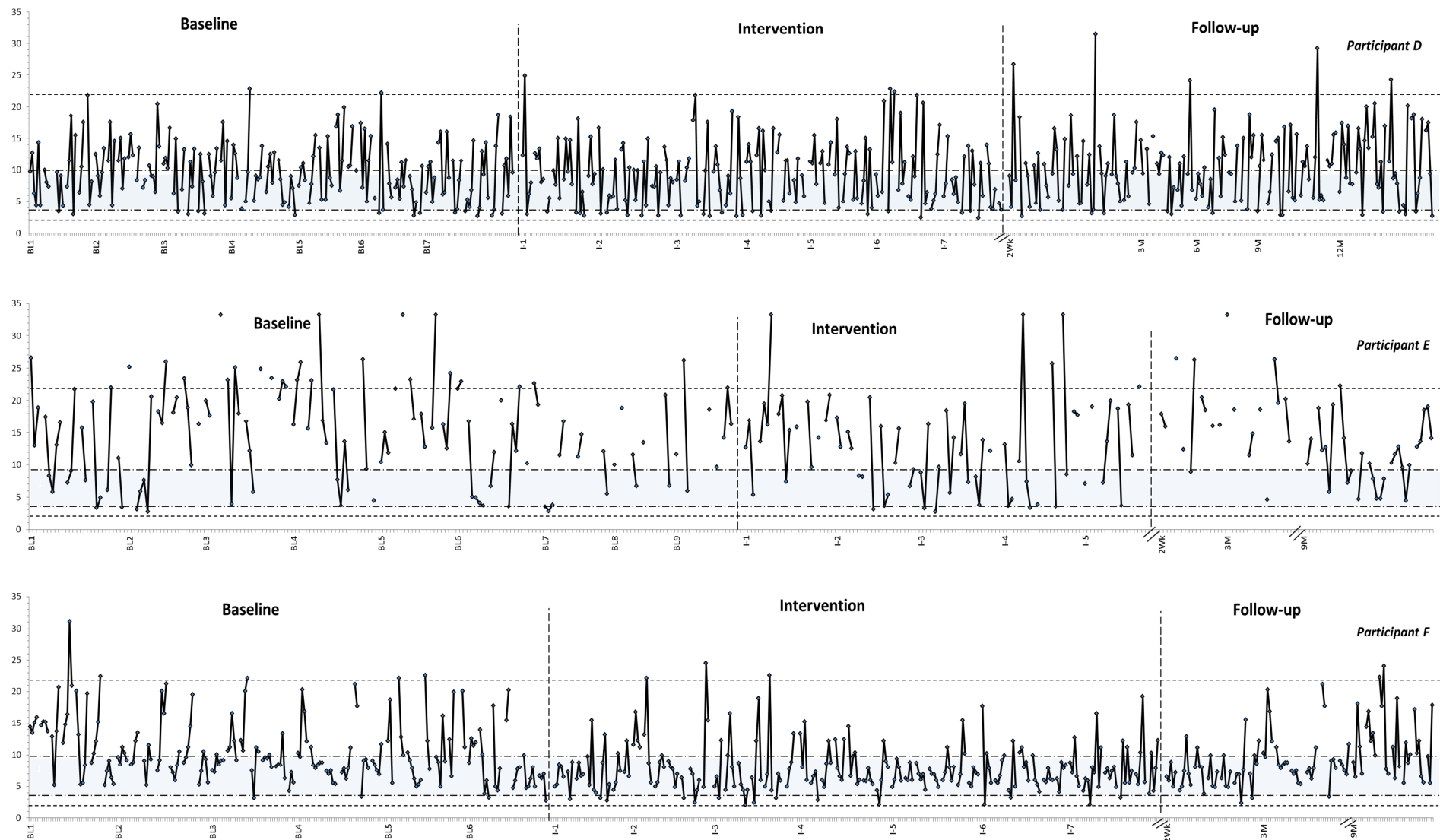
A measure of combined high and low BG (i.e., overall glucose variability) can be computed based on  $r(BG)$ . This is the Average Daily Risk Range (ADRR) (Kovatchev et al., 2006). This is calculated as follows. Let  $x_1^i, x_2^i, \dots, x_n^i$  be a series of  $n^i$  SMBG readings taken on day  $i, i = 1, 2, \dots, M$ . It is required that  $14 < M < 30$  and  $n^1, n^2, \dots, n^M \geq 3$ . Then, let  $LR^i = \max(rl(x_1^i), rl(x_2^i), \dots, rl(x_n^i))$  and  $HR^i = \max(rh(x_1^i), rh(x_2^i), \dots, rh(x_n^i))$  for day  $i, i = 1, 2, \dots, M$ .

The Average Daily Risk Range is then defined as

$$ADRR = \frac{1}{M} \sum_{i=1}^M [LR_i + HR_i]$$

## Appendix 4.4: Self-monitoring of Blood Glucose Charts





**Figure A.2.** SMOBG during baseline (BL), intervention (I), and follow-up (Wk = week; M= month).

